“A PROSPECTIVE, RANDOMIZED STUDY COMPARING THE ANTIEMETIC EFFECT OF INTRAVENOUS GRANISETRON AND ORAL GABAPENTIN IN PREVENTING POSTOPERATIVE NAUSEA AND VOMITING AFTER MIDDLE EAR SURGERY IN ADULTS”

Dissertation submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfilment for the award of the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

BRANCH X

INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE MADRAS MEDICAL COLLEGE

CHENNAI- 600003

APRIL 2016

CERTIFICATE OF THE GUIDE

This is to certify that the dissertation titled **"A PROSPECTIVE, RANDOMIZED STUDY COMPARING THE ANTIEMETIC EFFECT OF INTRAVENOUS GRANISETRON AND ORAL GABAPENTIN IN PREVENTING POSTOPERATIVE NAUSEA AND VOMITING AFTER MIDDLE EAR SURGERY IN ADULTS"** is a bonafide research work done by DR.V.BALAKRISHNAN in partial fulfilment of the requirement for the degree of DOCTOR OF MEDICINE in ANAESTHESIOLOGY.

Prof DR.M.VELLINGIRI,MD,DA

Institute of Anaesthesiology & Critical care

Madras medical college

Chennai-600003

Date:

Place:

CERTIFICATE

This is to certify that the dissertation titled "**A PROSPECTIVE, RANDOMIZED STUDY COMPARING THE ANTIEMETIC EFFECT OF INTRAVENOUS GRANISETRON AND ORAL GABAPENTIN IN PREVENTING POSTOPERATIVE NAUSEA AND VOMITING AFTER MIDDLE EAR SURGERY IN ADULTS"** submitted by DR.V.BALAKRISHNAN in partial fulfilment for the award of the degree of DOCTOR OF MEDICINE IN ANAESTHESIOLOGY by The Tamilnadu Dr.M.G.R MEDICAL UNIVERSITY, CHENNAI is a bonafide record of work done by him in the INSTITUTE OF ANAESTHESIOLOGY& CRITICAL CARE, Madras Medical College, during the academic year 2013 -2016 .

Prof DR.B.KALA, MD,DA
Director and Professor
Institute of Anaesthesiology& Critical care
Madras Medical College
Chennai -600003

DR.R.VIMALA,MD
The Dean
Madras Medical College
Chennai-600003

DECLARATION

I hereby declare that the dissertation titled **"A PROSPECTIVE, RANDOMIZED STUDY COMPARING THE ANTIEMETIC EFFECT OF INTRAVENOUS GRANISETRON AND ORAL GABAPENTIN IN PREVENTING POSTOPERATIVE NAUSEA AND VOMITING AFTER MIDDLE EAR SURGERY IN ADULTS"** has been prepared by me under the guidance of PROF.DR.M.VELLINGIRI,MD,DA, Professor of Anaesthesiology, Institute of Anaesthesiology & Critical care, Madras Medical college, Chennai, in partial fulfilment of the regulations for the award of the degree of M.D (Anaesthesiology),examination to be held in April 2016.

This study was conducted at Institute of Anaesthesiology & Critical care, Madras Medical College, Chennai.

I have not submitted this dissertation previously to any journal or any university for the award of any degree or diploma.

Date:

Place: Chennai DR.V.BALAKRISHNAN

ACKNOWLEDGEMENT

I am extremely thankful to Dr.R.VIMALAMD, The Dean, Madras Medical College, for her permission to carry out this study.

I am immensely thankful and indebted to Prof.DR.B.KALA, MD,DA, the Director and Professor, Institute of Anaesthesiology &Critical care, for her concern ,guidance and support in conducting this study.

I am extremely thankful to Prof DR.M.VELLINGIRI,MD,DA, for his concern ,inspiration, meticulous guidance, expert advice and constant encouragement in doing this study.

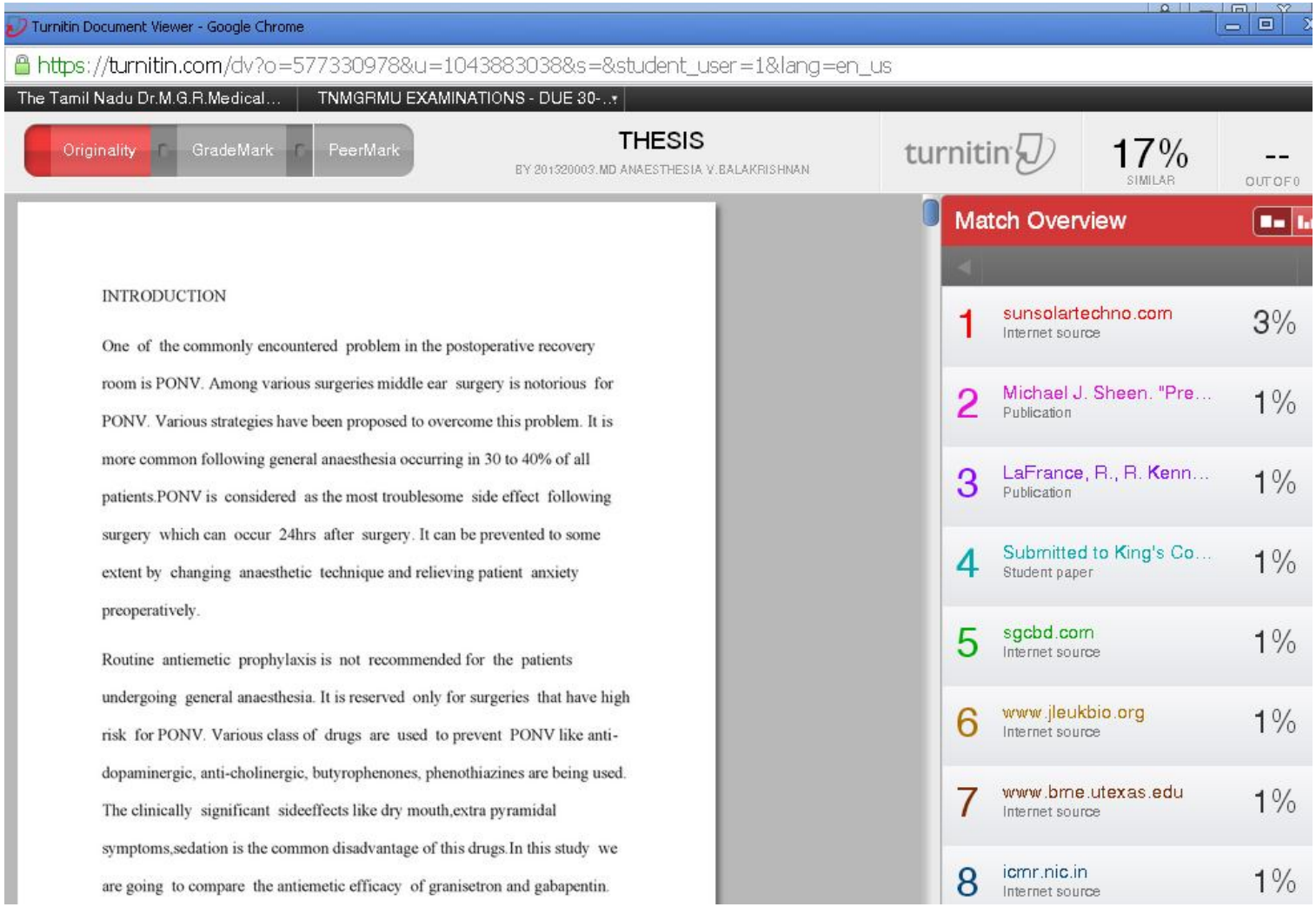
I am very much indebted to Assistant Prof. DR.CATHERINE RATHINASAMY M.D , DR. D. ASHOK KUMAR M.D, DR.D.SIVAKANTH for their timely guidance and invaluable help in conducting this study

I am thankful to institutional ethics committee for the approval and guidance for this study.

I am thankful to all my colleagues and friends for their help and advice in carrying out this study.

I am grateful to my family members and friends for their help and advice in carrying out this study.

Finally I am extremely thankful to Almighty and all the patients and family members for willingly submitting themselves for my study.


Turnitin Document Viewer - Google Chrome
https://turnitin.com/dv?o=577330978&u=1043883038&s=&student_user=1&lang=en_us
The Tamil Nadu Dr.M.G.R.Medical...
TNMGRMU EXAMINATIONS - DUE 30-...
Originality
GradeMark
PeerMark
THESIS
BY 201320003.MD ANAESTHESIA V.BALAKRISHNAN
turnitin
17%
SIMILAR
--
OUT OF 0
INTRODUCTION
One of the commonly encountered problem in the postoperative recovery room is PONV. Among various surgeries middle ear surgery is notorious for PONV. Various strategies have been proposed to overcome this problem. It is more common following general anaesthesia occurring in 30 to 40% of all patients.PONV is considered as the most troublesome side effect following surgery which can occur 24hrs after surgery. It can be prevented to some extent by changing anaesthetic technique and relieving patient anxiety preoperatively.
Routine antiemetic prophylaxis is not recommended for the patients undergoing general anaesthesia. It is reserved only for surgeries that have high risk for PONV. Various class of drugs are used to prevent PONV like anti-dopaminergic, anti-cholinergic, butyrophenones, phenothiazines are being used. The clinically significant sideeffects like dry mouth,extra pyramidal symptoms,sedation is the common disadvantage of this drugs.In this study we are going to compare the antiemetic efficacy of granisetron and gabapentin.
Match Overview
1 sunsolartechno.com Internet source 3%
2 Michael J. Sheen. "Pre... Publication 1%
3 LaFrance, R., R. Kenn... Publication 1%
4 Submitted to King's Co... Student paper 1%
5 sgcbd.com Internet source 1%
6 www.jleukbio.org Internet source 1%
7 www.bme.utexas.edu Internet source 1%
8 icmr.nic.in Internet source 1%

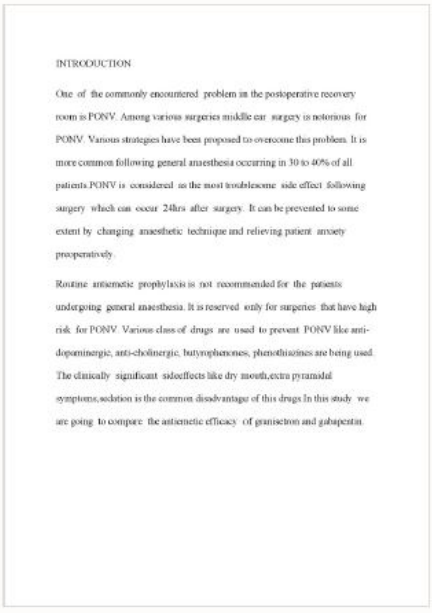
turnitin

Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

The first page of your submissions is displayed below.

Submission author:	201320003.md Anaesthesia V.BALA..
Assignment title:	TNMGRMU EXAMINATIONS
Submission title:	THESIS
File name:	BALKI_final_1.docx
File size:	484.07K
Page count:	75
Word count:	7,743
Character count:	42,814
Submission date:	29-Sep-2015 11:04PM
Submission ID:	577330978



INTRODUCTION

One of the commonly encountered problem in the postoperative recovery room is PONV. Among various surgeries middle ear surgery is notorious for PONV. Various strategies have been proposed to overcome this problem. It is more common following general anaesthesia occurring in 30 to 40% of all patients.PONV is considered as the most troublesome side effect following surgery which can occur 24hrs after surgery. It can be prevented to some extent by changing anaesthetic technique and relieving patient anxiety preoperatively.

Routine antiemetic prophylaxis is not recommended for the patients undergoing general anaesthesia. It is reserved only for surgeries that have high risk for PONV. Various class of drugs are used to prevent PONV like anti-dopaminergic, anti-cholinergic, butyrophenones, phenothiazines are being used. The clinically significant sideeffects like dry mouth,extra pyramidal symptoms,sedation is the common disadvantage of this drugs.In this study we are going to compare the antiemetic efficacy of granisetron and gabapentin.

S.NO	CONTENTS	PAGE NO
1	INTRODUCTION	1
2	AIM OF THE STUDY	2
3	PHYSIOLOGY OF NAUSEA AND VOMITING	3
4	CONSEQUENCES OF POST OPERATIVE NAUSEA AND VOMITING	9
5	FACTORS ASSOCIATED WITH POST OPERATIVE NAUSEA AND VOMITING	10
6	ROLE OF 5HYDROXY TRYPTAMINE (5HT) IN POST OPERATIVE NAUSEA AND VOMITING	15
7	RECENT TRENDS IN MANAGEMENT OF POST-OPERATIVE NAUSEA AND VOMITING	17
8	PHARMACOLOGY OF GRANISETRON	19
9	PHARMACOLOGY OF GABAPENTIN	22
10	REVIEW OF LITERATURE	25
11	MATERIALS AND METHODS	31
12	OBSERVATIONS AND RESULTS	34
13	DISCUSSION	71
14	SUMMARY	75
15	CONCLUSION	76
	BIBLIOGRAPHY	
	MASTER CHART	

ABSTRACT

BACKGROUND:

The incidence of postoperative nausea and vomiting (PONV) after middle ear surgery is high. In this study we want to compare the effects of intravenous Granisetron and oral gabapentin as a premedication before surgery in patients undergoing middle ear surgeries.

MATERIALS AND METHODS:

We enrolled 60 patients that were randomly divided into the two groups of 30 in each. Group I received Granisetron 3 mg iv 2 minutes before induction of anesthesia; Group II received oral Gabapentin 300 mg 1 hour before induction. The incidence and severity of PONV were recorded each 30 minutes for 1^{st} 6 hours in the post-anesthesia care unit (PACU) and each 2^{nd} hourly 10 hours and 4^{th} hourly for next 8 hours. The severity of nausea was assessed by visual analogue scale (VAS).

RESULT:

The incidence and severity of nausea and vomiting at different time intervals in Groups I and Group II was not significant. There was no significant difference in the incidence of side effects like respiratory depression, apnea, extra pyramidal disorders, drowsiness, dizziness, vertigo and headache in two groups.

CONCLUSION:

The study was shown that using Gabapentin and Granisetron have equal anti-emetic effects, These submit the efficiency of these drugs in preventing Post operative nausea and vomiting (PONV).

Key Words:

$5HT_3$ receptors, Gabapentin, Granisetron, post operating nausea and vomiting (PONV), visual analogues scale

INTRODUCTION

One of the commonly encountered problem in the postoperative recovery room is Post Operative Nausea and Vomiting. Among various surgeries middle ear surgery is notorious for Post Operative Nausea and Vomiting. Various strategies have been proposed to overcome this problem. It is more common following general anaesthesia occurring in 30 to 40% of all patients[27].Post Operative Nausea and Vomiting is considered as the most troublesome side effect following surgery which can occur 24hrs after surgery. It can be prevented to some extent by changing anaesthetic technique and relieving patient anxiety preoperatively.

Routine antiemetic prophylaxis is not recommended for the patients undergoing general anaesthesia. It is reserved only for surgeries that have high risk for Post Operative Nausea and Vomiting. Various class of drugs are used to prevent Post Operative Nausea and Vomiting like anti-dopaminergic, anti-cholinergic, butyrophenones, phenothiazines are being used. The clinically significant side effects like dry mouth, extra pyramidal symptoms, sedation is the common disadvantage of this drugs. In this study we are going to compare the antiemetic effect of Granisetron and Gabapentin.

AIM

The aim of this clinical trial is to compare the efficacy of prophylactic intravenous administration of Granisetron 3mg versus Gabapentin 300mg orally in preventing Post Operative Nausea and Vomiting in patients undergoing middle ear surgeries in adults undergoing general anaesthesia.

PHYSIOLOGY OF NAUSEA AND VOMITING

NAUSEA:

Nausea is conscious recognition of subconscious excitation in an area of medulla closely related to vomiting centre[15]. It can also be caused by

1. Irritative impulse from GI tract
2. Impulses from cerebral cortex to initiate vomiting.

VOMITING:

Vomiting is an act by which upper GI tract rids itself of its contents when any part of upper tract becomes excessively irritated or overdistented[15].

RETCHING:

It is defined as laboured rhythmic activity of the respiratory musculature that usually precedes or accompanies vomiting.

PHASES OF VOMITING:

There are two primary phases involved in emesis:

1. The prodromal phase,
2. The vomiting phase.

PRODROMAL PHASE:

1. It may be accompanied by nausea,
2. Stimulation of sympathetic system leads to tachycardia, pupillary dilatation and cutaneous vasoconstriction[2].
3. Stimulation of parasympathetic system leads to salivation and gastro-intestinal motor activity.

VOMITING PHASE:

The first effects after stimulating vomiting centre are

1. a deep breath,
2. raising of hyoid bone and larynx to pull upper oesophageal sphincter open[16],
3. closing of glottis to prevent vomitus enter into lungs,
4. lifting of soft palate to close posterior nares and afterwards there is a strong downward contraction of diaphragm along with simultaneous contraction of all abdominal muscles. This squeezes stomach between diaphragm and abdominal muscles building up intragastric pressure to a high level. Finally lower oesophageal sphincter relaxes completely causing expulsion of gastric contents upward through oesophagus[16].

VOMITING CENTRE:

It is located in the medulla oblongata in close proximity to the respiratory centre, salivation nuclei, vestibular nuclei, vasomotor nuclei. It receives stimulus from chemoreceptor trigger zone, nucleus Tractus solitarius, afferents from the abdomen , vestibular system and from certain higher centres.

CHEMORECEPTOR TRIGGER ZONE:

It lies within the Area Postrema(AP) of the brain stem which is a "U"shaped circumventricular organ located bilaterally on the floor of the fourth ventricle. The blood brain barrier in this region is poorly developed[15].

ABDOMINAL VISCERAL AFFERENTS:

The vagus nerve which is present carries the afferent signals from the abdomen which triggers the emetic response. The afferent impulses carried by the vagus nerve stimulates the emetic centre through the nucleus Tractus solitarius(NTS).

The enterochromaffin cells which is present in the gut release serotonin in response to the irritants which activates vagal afferents. The vagal afferents are of two types:

1. Chemoreceptors which is present in the mucosa of the upper gut and the local irritants stimulates it.
2. Mechanoreceptors : It is present in the wall of the gut which is activated by contraction and distension of the gut[2]

HIGHER CENTRES:

Emesis can also be induced by unpleasant smell, pain, taste and sight.

VESTIBULAR SYSTEM:

Activation of receptors due to motion sickness which stimulates labyrinth of inner ear signals vestibular nuclei in the cerebellum which stimulates chemoreceptor trigger zone triggers the vomiting centre that leads to emesis[15].

MOTOR COMPONENTS OF VOMITING REFLEX :

The motor components are mediated through somatic and autonomic nerves. Sensory impulses from pharynx , oesophagus, stomach are carried to the vomiting centre[16].

Sensory signals from pharynx, oesophagus, upper part of small intestine

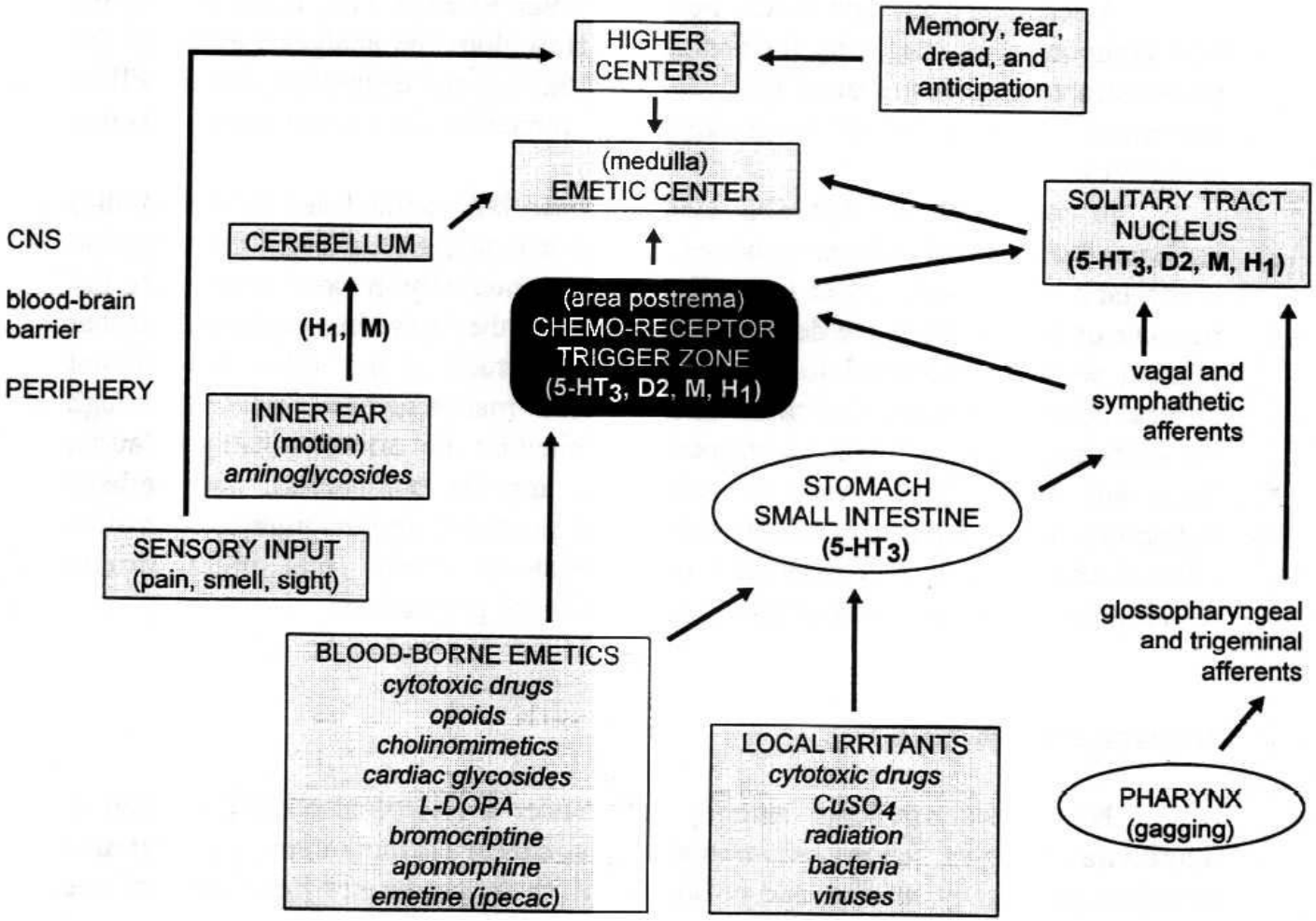
Vagal and sympathetic afferent nerve fibres

Vomiting centre(multiple nuclei in the brainstem)

5^{th},7^{th},9^{th},10^{th},12^{th} cranial nerves

Through vagal and sympathetic nerves to lower tract and through spinal nerves to diaphragm and abdominal muscles.

EMETIC PATHWAYS AND CENTRES RESPONSIBLE FOR EMESIS



CONSEQUENCES OF POST OPERATIVE NAUSEA AND VOMITING

Patient :

Postoperative pain and discomfort : The fluid and food intake is delayed

Physiological:

Sweating , increased in heart rate, salivation , abnormal cardiac rhythms and pallor.

Medical:

Electolyte imbalance like hypokalemia , metabolic alkalosis due to hyponaterimia , dehytration , orthostatic hypotension and interuption of diet.

Surgical:

Wound dehiscence and bleeding, oesophageal tears, increased intracranial and intraocular pressure, anastamotic grafts disruption,

Anaesthesia:

Aspiration pneumonia can occur.

Hospital stay / cost:

Unexpected hospital admission and delay in discharge.

FACTORS ASSOCIATED WITH POSTOPERATIVE NAUSEA AND VOMITING

PATIENT FACTORS:

Gender :

Adult females are having three times increased incidence and severity of postoperative nausea and vomiting than adult males.

Age :

In infantile age group the incidence of Post Operative Nausea and Vomiting is less compared with late childhood where it is 34-51% and it remains constant throughout adult age group upto eigth decade[26] .

Smokers :

One might predict that smokers have higher risk of Post Operative Nausea and Vomiting than nonsmokers , Cohen and associates found that nonsmokers were 1.8 times more likely than smokers to have Post Operative Nausea and Vomiting[26].

History of Post Operative Nausea and Vomiting or motion sickness:

The patients with history of motion sickness or post operative nausea and vomiting in previous anaesthesia are more likely to develop Post Operative Nausea and Vomiting[26].

Anxiety :

Infants and children are more anxious because of that they swallow large volume of air and anaesthetic gases during induction which results in gastric distension and are prone to develop vomiting, anxiety also delays gastric emptying.

Body habitus:

Obese patients are more likely to develop Post Operative Nausea and Vomiting than asthenic patients.

Menstruation :

Studies have reported that women are more susceptible to Post Operative Nausea and Vomiting during first seven days of menstrual cycle[7].

SURGICAL FACTORS:

Middle ear surgery:

Due to increased middle ear pressure secondary to nitrous oxide , the incidence of Post Operative Nausea and Vomiting increases and the mechanism is the activation of vestibular system afferent pathway especially if the system is sensitized by opiods. Another pathway is the nerve supplying the tympanum (ie) the auricular branch of vagus nerve- Arnold`s Nerve ,its activation leads to emesis.

Adenotonsillectomy :

The irritation of trigeminal nerve during surgery and the irritant effect of swallowed blood on the oesophago-gastric chemoreceptors results in higher incidence of Post Operative Nausea and Vomiting.

Abdominal surgery:

The direct effect of vagal afferents and the release of 5HT from the enterochromaffin cells due to surgical manipulation of intestine stimulates vomiting centre which results in emesis.

Post Operative Nausea and Vomiting incidence over 24 hours was 42% for “emetogenic procedures” compared with other surgical procedures(36%)[26].

Gynaecological surgery

Laproscopic surgeries like abdominal hysterectomy is associated with increased incidence of Post Operative Nausea and Vomiting (upto 65 -77%).

Opthalmic surgery

Strabismus surgery is the common surgery associated with high incidence of Post Operative Nausea and Vomiting

Duration of anaesthesia

Increase in the duration of the surgery is associated with higher incidence and severity of postoperative nausea and vomitting.

ANAESTHETIC FACTORS

Premedication

Anticholinergics like Glycopyrolate cause more Post Operative Nausea and Vomiting than Atropine. Hence in patients with predisposing factors for Post Operartive Nausea and Vomiting, Atropine is preferred over Glycopyrolate.

Opioids

All opioids in general cause emesis of which Morphine and Pethidine cause maximum emesis. It is mediated through μ-receptors in Area postrema. It also increase the sensitivity of emetic reflex by labrythine stimulation. Morphine and other opioids enhance the release of 5HT from small intestine.

Benzodiazepines

In general it does not causePost Operartive Nausea and Vomiting though temazepam has found to increase the risk of Post Operartive Nausea and Vomiting.

I V Induction agents

Out of various induction agents available Propofol is associated with least incidence of Post Operative Nausea and Vomiting. Thiopentone sodium is better than etomidate in reducing the incidence of Post Operartive Nausea and Vomiting[26].

Intubation

During insertion of airway pharangeal mechanoreceptors are stimulated via glossophrangeal nerve and these project into the brainstem.

Inhalational anaesthetic agents

Nitrous oxide (N_2O)

Nitrous oxide by its action on central opioid receptors , gut distension and increased pressure in the middle ear increase the incidence of Post Operative Nausea and Vomiting.

Volatile anaesthetic agent

Modern volatile agents like Isoflurane , Sevoflurane , Desflurane has the less incidence of Post Operartive Nausea and Vomiting than older agents.

Neuromuscular blocking drugs

In general these drugs does not have effects on Post Operartive Nausea and Vomiting but reversal drug Neostigmine has been implicated with increased incidence of Post Operartive Nausea and Vomiting.

Anaesthetic techinque

Regional anaesthesia is associated with less incidence of Post Operartive Nausea and Vomiting than general anaesthesia.

Movements

Post Operative Nausea and Vomiting can occur when there is a sudden jerky movements while shifting the patients.

ROLE OF 5HT IN POST OPERATIVE NAUSEA AND VOMITING

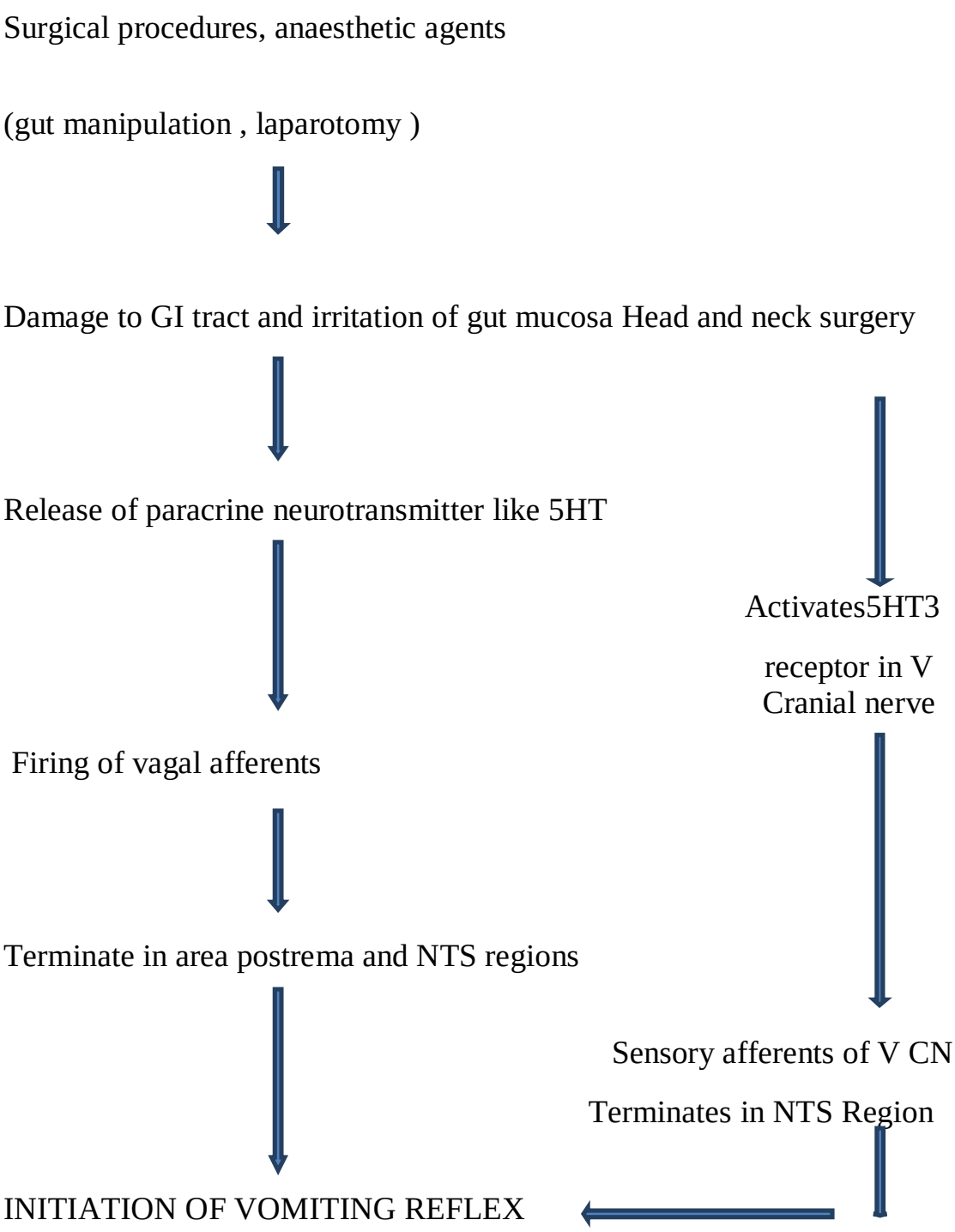
Both peripheral and central mechanisms are involved in the control of emesis. The 5HT and $5HT_3$ receptors are involved in eliciting the mechanism for emesis which has been proven in the animal model[9].

The discovery of $5HT_3$ receptor antagonists in control of chemotherapy and radiotherapy induced emesis has led to the clinical evaluation of Granisetron in preventing postoperative nausea and vomiting[9].

In the CNS the $5HT_3$ receptors are more abudant in the NTS-AP regions. The chemoreceptor trigger zone is located in this region.

Most vagal afferents from the periphery enter the brain from GIT where the concentration of $5HT_3$ receptors are higher.

PERIPHERAL PATHWAYS:



RECENT TRENDS IN THE MANAGEMENT OF POST OPERATIVE NAUSEA AND VOMITING

Post Operative Nausea and Vomiting is the result of interaction of many factors like type of surgery, age, gender , use of opioids , anaesthetic agents etc. It is apparent that single antiemetic drug will not be effective in all conditions.

Many pharmacological and non-pharmacological therapies has been evaluated in the treatment of Post Operative Nausea and Vomiting.

PHARMACOLOGICAL PROPHYLAXIS

1. Butyrophenones (eg . Droperidol) is a dopamine receptor blocker which is present in CTZ. Use of droperidol is associated with the side effect of QT prolongation and torsades de pointes syndrome.
2. Metaclopramide is an another dopamine receptor blocker present in CTZ. It acts by shortening the bowel transit time and blocks seratonin receptors at high doses. The disadvantage of the drug is extrapyramidal symptom as side effect.
3. Dimenhydrinate an antihistaminic is also used as an antiemetic.
4. Scopolamine an anticholinergic can block muscarinic recaptors responsible for emesis.
5. Recently , Diclectin[26] is found to be effective as Ondansetron. It contains doxylamine succinate, with 10mg Pyridoxine

hydrochloride. Pyridoxine may have intrinsic antiemetic property and may also be synergestic with antihistamines.

6. Aprepitant a NK -1 receptor[26] antagonist has been approved for treatment of Post Operative Nausea and Vomiting. It blocks NK-1 receptors in the CNS and PNS results in prevention of emesis.

7. The futured therapies in prevention of Post Operartive Nausea and Vomiting are the use of cannabinoids and peripheral opioid antagonist – Naloxone.

The baseline risk factors which can be reduced are as follows

1. Use of regional anaesthesia
2. Use of propofol for induction and maintenance of anaesthesia
3. Avoidance of Nitrous oxide (N2O)
4. Avoidance of volatile agents
5. Reduction of intraop and postop opioids

NON – PHARMACOLOGIC THERAPY

In selected group of patients , Acupunture has been found to be effetive in preventing Post Operative Nausea and Vomiting[10].

PHARMACOLOGY OF GRANISETRON

INTRODUCTION

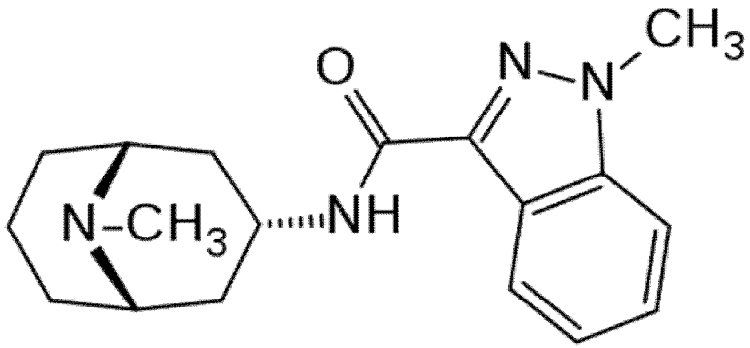
Granisetron is a selective $5HT_3$ receptor antagonist which is synthesized in 1988 and the drug was approved by FDA in 1994[21].

CHEMISTRY

Formula $C_{18}H_{24}N_4O$

Molecular weight: 312.4g/mol

MOLECULAR STRUCTURE OF GRANISETRON HYDROCHLORIDE



PHARMACOLOGY

It is a $5HT_3$ receptor antagonist with a main action at the vomiting centre at medulla. It mainly reduces the activity of vagus nerve hence used for chemotherapy induced nausea and vomiting.

Actions

There is no demonstrable effect on heart rate, cardiac output, blood pressure and electrocardiogram.

Pharmacokinetics

It may be given orally,intravenously and transdermal patch.

Absorption : Oral absorption in an empty stomach is 30%. Mean plasma half-life is 7 to 9 hours.

Distribution : Granisetron freely distributes between plasma and red blood cells. It is 65% bound to plasma proteins.

Metabolism : It is metabolized in the liver . The major route involves N-demethylation and aromatic ring oxidation followed by conjugation. Metabolism is modulated by cytochrome P450 3A.

Elimination : Predominantly by hepatic metabolism, 11% of the drug eliminated unchanged in urine and no dose change required in renal failure[18].

PREPARATION

Oral: 1 mg or 2 mg of Granisetron hydrochloride.

Parenteral : Isotonic aqueous solution of Granisetron hydrochloride 3mg/3ml vial.

THERAPEUTIC USES

1. It is used in control of nausea and vomiting due to chemotherapy induced emesis.

2. Used for both acute and chronic illness of postoperative nausea and vomiting.

3. Used to treat acute gastroenteritis induced vomiting

CONTRAINDICATIONS

Hypersensitivity to any of the components.

ADVERSE EFFECTS

Granisetron is generally well tolerated. Headache, dizziness are the side effects. Constipation is the commonest complaint[18].

WARNING: Serotonin syndrome development has been noticed with $5HT_3$ antagonist.

DOSE: Optimum dose for intravenous administration is 3mg in adults.

PHARMACOLOGY OF GABAPENTIN

INTRODUCTION

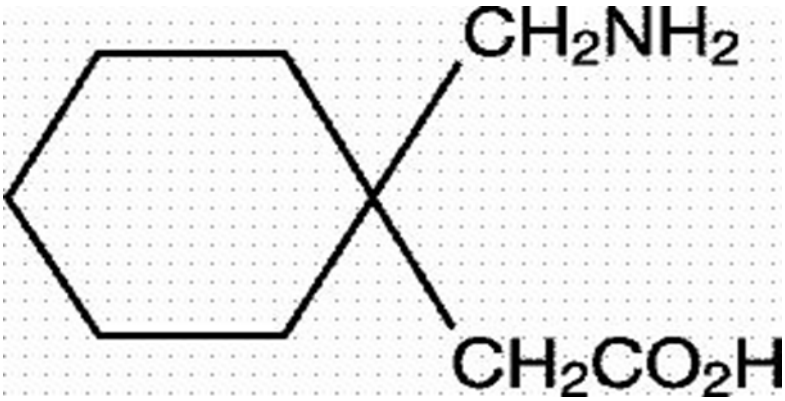
Gabapentin is an amino acid analogue of GABA, the neurotransmitter. It was originally used as spasmodic but recently more used for partial seizures and for analgesia. It was approved by FDA in 1993.

CHEMISTRY

Formula: C9H17NO2

Molecular weight: 171.2 g/mol

MOLECULAR STRUCTURE OF GABAPENTIN



PHARMACOLOGY

Mechanism of action

Though it is similar in similarity to GABA, it do not act directly on GABA receptor. It modifies the synaptic or postsynaptic release of GABA. It binds avidly to α2δ subunit of voltage gated calcium channels. It also acts presynaptically and decreases glutamate release[21].

The mechanism by which it reduces the Post Operative Nausea and Vomiting is unclear, the postulated mechanism is, it reduces the activity of tachykinin neurotransmitter, decrease the calcium influx in Area postrema, by opioid sparing effect, by reducing the inflammation at the surgical site[5].

Pharmacokinetics

Absorption : The drug is absorbed orally and is non linear and dose dependent at very high doses. The bioavailability of the drug is 27-60%.

Distribution : The drug is not bound to plasma proteins , hence the drug interaction is negligible[21].

Metabolism : It is not metabolized and does not induce liver enzymes.

Elimination : It is eliminated by the kidneys and it is linear. It is excreted unchanged in urine.

Half life of the drug is 5 to 8 hours.

Preparation : it is available as

Capsule- 100mg, 300mg and 400 mg

Tablet – 300mg, 600mg and 800mg

Oral solution – 250mg /5ml.

USES

It is used in the treatment of

1. Partial seizures
2. Post herpetic neuralgia
3. Restless leg syndrome
4. Cocaine withdrawal
5. Insomnia
6. Diabetic neuropathy
7. Tremors in multiple sclerosis
8. Cancer related hot flushes
9. Amyotrophic lateral sclerosis

Adverse effects: drowsiness, dizziness and fatigue[21].

REVIEW OF LITERATURE

1. Fuji et al 2003;25: 1142-9 published a randomized double blind study in British Journal of Anaesthesia regarding the efficacy and safety of Granisetron , Droperidol and combination of both in preventing Post Operative Nausea and Vomiting for patients undergoing breast surgery. They found the incidence of Post Operative Nausea and Vomiting during first 24hours of postoperative period as 18% with Granisetron , 38% with Droperidol and 4% with a combination of Granisetron and Droperidol when given immediately before induction of anaesthesia and a standard anaesthetic technique was used[13]
2. Pandey CK et al 2006;52:97-100 conducted a randomized , double blind placebo controlled study to evaluate the effect of Gabapentin 600mg orally 2 hours before surgery in prevention of Post Operative Nausea and Vomiting in patients undergoing laparoscopic cholecystectomy. A total of 250 patients were randomly assigned into placebo and Gabapentin group. They concluded that Gabapentin effectively suppressed Post Operative Nausea and Vomiting and rescue analgesic requirement postoperatively[32].

3. Khademi S et al 2010;19:57-60 conducted a preoperative randomized double blind placebo controlled study to evaluate the effect of Gabapentin 600mg orally on severity of Post Operative Nausea and Vomiting in patients undergoing open cholecystectomy. A total of 90 patients were randomly assigned into placebo and Gabapentin group. They concluded that patients in Gabapentin group had significant decreased Post Operative Nausea and Vomiting and analgesic requirement in the postoperative period[23].
4. Ajori et al 2012;285:677-82 conducted a double blinded randomized clinical trial to evaluate the effect of pre-emptive use of Gabapentin 600 mg orally on postoperative pain and Post Operative Nausea and Vomiting, rescue analgesia use and antiemetic drug requirement in patients undergoing abdominal hysterectomy. A total of 140 patients were randomly assigned into placebo and Gabapentin group. They concluded that patients in Gabapentin group had significant decreased Post Operative Nausea and Vomiting and antiemetic requirement in the postoperative period[3].
5. AshutoshSayana et al 2012;2:2231-4423 their comparative study of Metoclopramide, Ondansetron and Granisetron in prophylaxis of Post Operative Nausea and Vomiting in patients undergoing laparoscopic cholecystectomy under general anaesthesia. According to them there was no statistically significant difference was found among three

groups in 0 – 2 hours and beyond 12 hours postoperative period , but 2-12 hour postoperative period showed a statistically significant , more effective prevention of Post Operative Nausea and Vomiting in Granisetron group[6].

6. Firdose et al 2012;32 conducted a prospective , randomized double blind study in evaluating the efficacy of Granisetron with or without Dexamethasone for elective head and plastic surgery showed a statistically significant difference in the occurrence of postoperative nausea and vomiting. Although the addition of Dexamethasone further decreased the incidence of nausea and vomiting upto 24 hours but statistically significant difference was found[11].
7. Mohammed MH et al 2014;30:225-8 conducted a randomized double blind, placebo controlled study to evaluate the effect of pre-emptive use of Gabapentin 20mg / kg on severity of POV in paediatric patients (4-8 years) undergoing adenotonsillectomy. A total of 144 patients were randomly assigned to Gabapentin and placebo group. They concluded that Gabapentin effectively reduced POV and analgesic requirement postoperatively[29].
8. Nethra et al 2014;4:2249-6467 in international journal of pharmacology and therapeutics had published a research article stating the results of Granisetron with Dexamethasone and Ondansetron with Dexamethasone and placebo in reducing Post Operative Nausea and

Vomiting for patients undergoing gynaecological procedures. According to them, the incidence of Post Operative Nausea and Vomiting for females undergoing gynaecological procedure is 72% . A comparative study of the above three groups showed that the incidence of Post Operative Nausea and Vomiting was 60% , 12% and 12% for placebo , Granisetron , Ondansetron groups respectively. The granisetron100mg + Dexamethasone 8mg , Ondansetron 4 mg + dexamethasone 8 mg showed no statistical difference in preventing Post Operative Nausea and Vomiting when administered prophylactically , placebo group showed higher incidence of Post Operative Nausea and Vomiting[30].

9. S.Achuthan et al 2015;114:588-97 conducted a quantitative analysis of evidence from seventeen randomized placebo controlled trials involving administration of Gabapentin preoperatively in patients undergoing elective abdominal procedures. Their analysis assessed nausea, vomiting and rescue antiemeticuse in postoperative period and conducted from their analysis that the relative risk for nausea as 0.76,0.62 for vomiting, o.71 for composite Post Operative Nausea and Vomiting and 0.6 for rescue antiemetic use. They had concluded that preoperative Gabapentin helps in preventing Post Operative Nausea and Vomiting in patients undergoing abdominal surgeries[5].

10. MortezaHeidari et al 2015;4:22 studied the effect of Granisetron and Gabapentin in preventing Post Operative Nausea and Vomiting in patients undergoing middle ear surgeries in adults under general anaesthesia in three groups with control as the third group , the study was conducted in 90 patients. They concluded that the both drugs have equal antiemetic effect in preventing Post Operative Nausea and Vomiting compared with control group[28].

SAMPLE SIZE CALCULATION

Sample size was determined based on

Study

Granisetron versus gabapentin in preventing postoperative nausea and vomiting after middle ear surgery in adults: A double blinded randomized clinical trial study

Authored by

Morteza Heidari et al

Published in

Adv Biomed Res 2015;4:22.

In this study the ASA classification between the two groups had a difference of 19%.

Description:

- The confidence level is estimated at 95%
- with a z value of 1.96
- the confidence interval or margin of error is estimated at +/-10
- Assuming that 80 percent of the sample will have the specified attribute p% =19 and q%=81

  $n = p\% \times q\% \times [z/e\%]^2$

  $n = 19 \times 81 \times [1.96/10]^2$

  $n = 59$

Therefore 59 is the minimum sample size required for the study.

In our study 60 subjects were chosen (n=30 in Gabapentin arm and n=30 in Granisetron arm)

MATERIALS AND METHODS

This was a randomised, double blinded study conducted at the Institute of Anaesthesiology and Critical Care, Madras Medical College, Chennai. Sixty patients between ages of 18 to 60 yrs, who were scheduled to undergo elective middle ear surgeries under general Anaesthesia were included in the study.

Informed consent regarding the procedure was obtained from all patients. Pre-operatively the patients were educated about the visual analogue scale. They were shown the scale and were taught how to rate the severity of nausea post-operatively. The scale was graded from 0 to 10cm. “0” indicated no nausea at all and “10” was very severe nausea. The scale was divided into 3 equal portions to denote mild, moderate and severe nausea respectively.

The inclusion criteria included the following：

- ASA-1,2
- Age group 18-60 years.
- Undergoing any middle ear surgery.

The exclusion criteria were as follows:

- Pregnant females
- History of addiction or using antiemetics
- BMI>30
- Any cerebellar problems
- Uncontrolled bleeding during surgery

- History of Post Operative Nausea and Vomiting after previous surgery
- History of motion sickness
- Duration of surgery > 2 hrs

The patient were premedicated with 0.01mg/kg of Glycopyrolate and 2µg/kg of Fentanyl after connecting the monitors and securing intravenous line. The patients were randomly allocated to two groups. Group A and Group B.

Group A received 3mg iv in a volume of 3 ml 2 minutes prior to induction and group B received 3mg Gabapentin 1 hour before induction. After 5 minutes of preoxygenation anaesthesia was induced with 5mg/kg of 2.5% iv Thiopentone sodium , intubation was facilitated by giving 0.5mg/kg of Atracurium and ventilated for 5 minutes and then trachea was intubated with cuffed endotracheal tube of appropriate size. Anaesthesia was maintained with intermittent positive pressure ventilation with 60:40 nitrous oxide and oxygen, 0.8 to 1.2% Isoflurane and Atracurium was used for muscle relaxation. Increment doses of fentanyl were given as necessary.

INTRA-OPERATIVE MONITORING

During intraoperatively the heart rate, ,non-invasive blood pressure, oxygen saturation monitoring were done. Intraoperative fluid balance was maintained with 10ml/kg/hr of normal saline. Blood loss was assessed using weighing method and blood was replaced if the loss is >10% of patients blood volume.

Blood pressure, heart rate , oxygen saturation were recorded every 5 minutes during the procedure. At the end of surgery inj.Neostigmine 0.05mg/kg and inj.Glycopyrolate 0.01mg/kg given intravenously to reverse the neuromuscular blockade. The duration of surgery was noted. The patient was shifted to post anaesthetic care unit (PACU) after recovery.

Heart rate, blood pressure and oxygen saturation(SpO2) were monitored for every half an hour for the first 6hrs and then every 2 hrs. Nausea and vomiting were assessed soon after recovery and in the PACU for every ½ hour. for first 6 hour and then 2^{nd} hourly for next 10hoursand then 4^{th} hourly for next 8 hrs. Nausea is the subjective sensation which is assessed by using visual analogue scale (VAS) The patients were taught already about how to rate their nausea in the visual analogue scale and according to that nausea was classified as mild, moderate and severe.

Severity of vomiting was classified as follows:

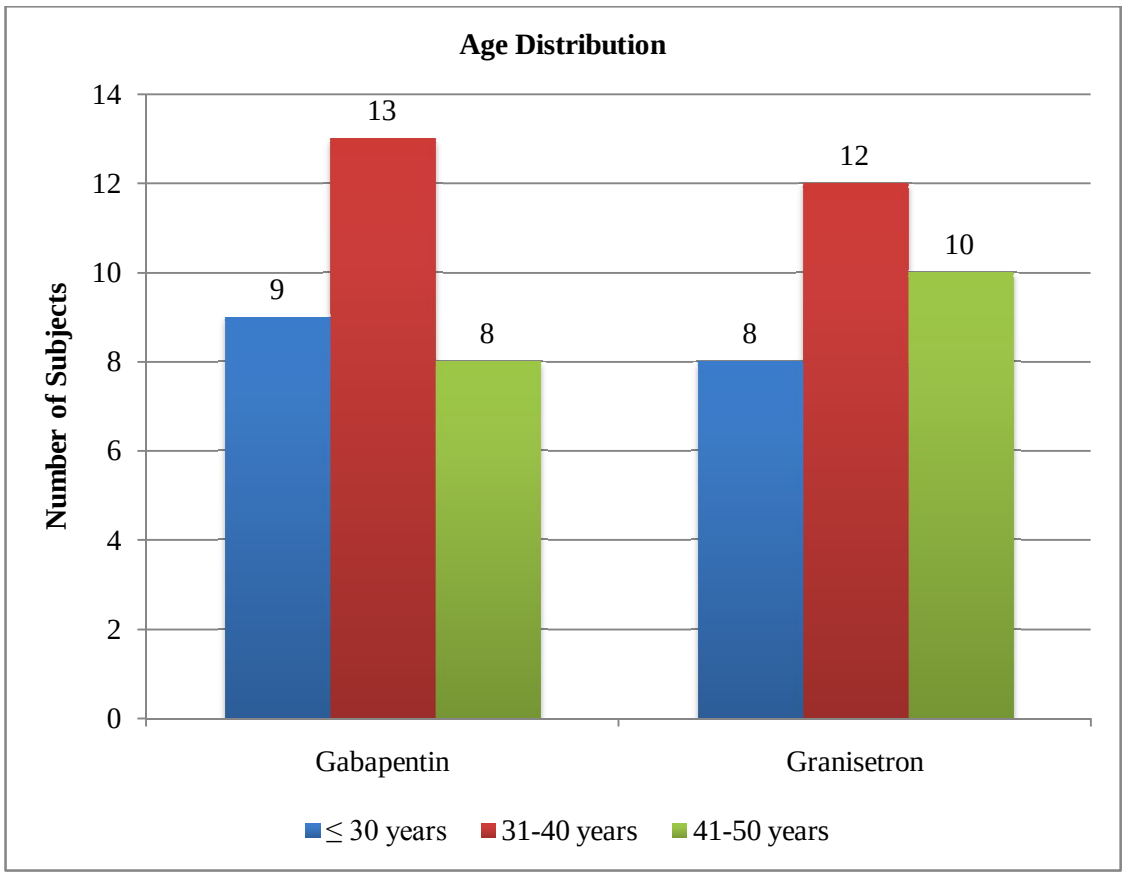
- Mild:1 - 2 episodes;
- Moderate: 3-4 episodes;
- Severe:more than 4 episodes.

In case of severe vomiting inj. Metoclopramide 10 mg iv was given as a rescue antiemetic. Patients were also asked for any other complaints like headache, dizziness and appropriate treatment was given.

DATA ANALYSIS

Descriptive statistics was done for all data and were reported in terms of mean values and percentages. Suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t test.. Categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analysed using SPSS version 16 and Microsoft Excel 2007.

Age Distribution

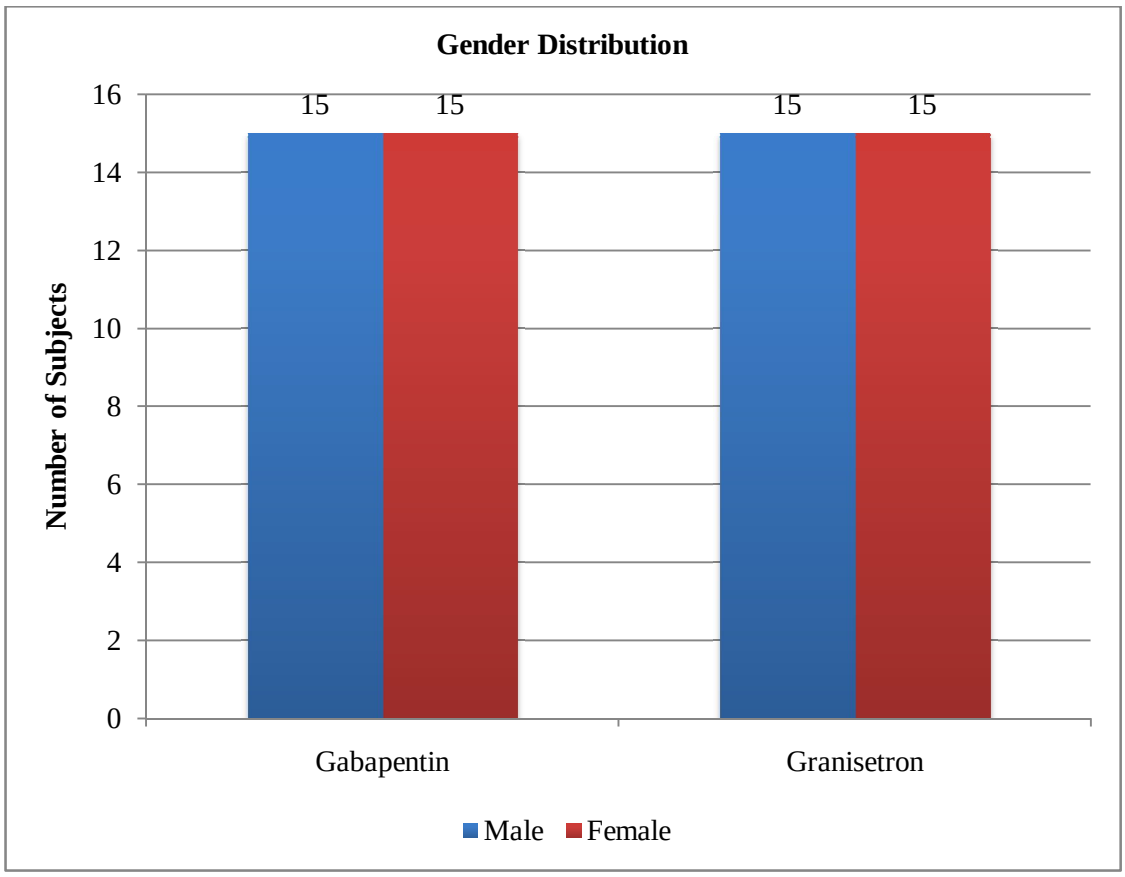


Age Distribution	Gabapentin	%	Granisetron	%
≤ 30 years	9	30.00	8	26.67
31-40 years	13	43.33	12	40.00
41-50 years	8	26.67	10	33.33
Total	30	100	30	100

Age Distribution	Gabapentin	Granisetron
N	30	30
Mean	34.87	34.83
SD	8.44	8.56
P value Unpaired t Test		0.9879

Majority of the Gabapentin group patients belonged to the 31-30 years age class interval (n=13, 43.33%) with a mean age of 34.87 years. In the Granisetron group patients, majority belonged to the same age class interval (n=12, 40%) with a mean age of 34.83 years. The association between the intervention groups and age distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

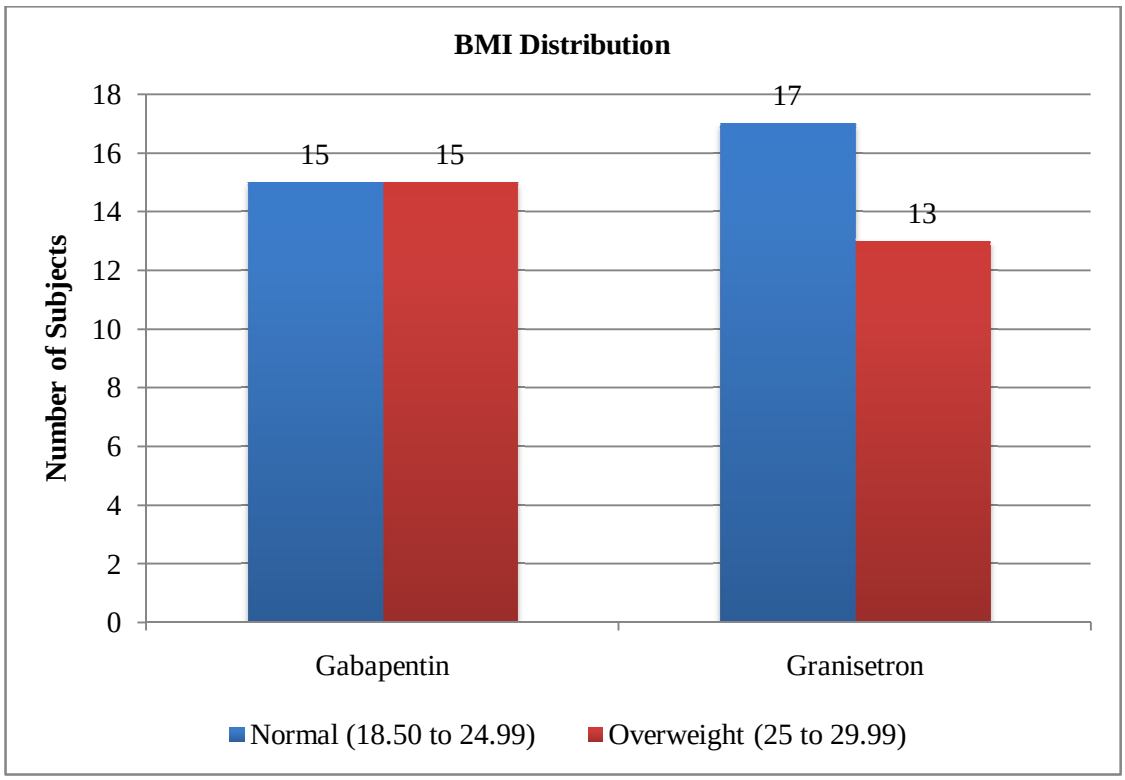
Gender Distribution



Gender Distribution	Gabapentin	%	Granisetron	%
Male	16	53.33	15	50.00
Female	14	46.67	15	50.00
Total	30	100	30	100
P value Chi Squared Test			0.9999	

Majority of the Gabapentin group patients belonged to the male gender class interval (n=16, 53.33%). In the Granisetron group patients, majority belonged to the same gender class interval (n=15, 50%). The association between the intervention groups and gender distribution is considered to be not statistically significant since $p > 0.05$ as per chi squared test

BMI Distribution

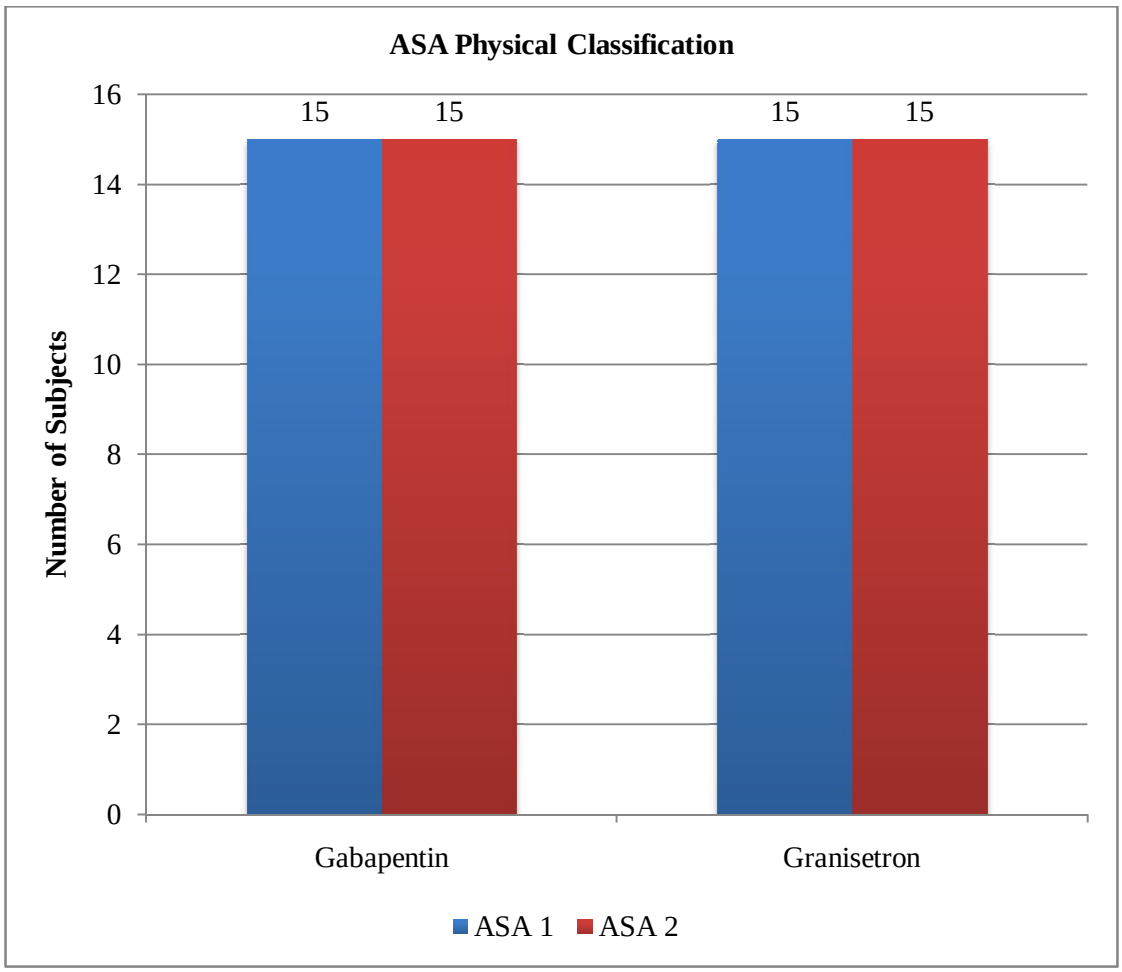


BMI Distribution	Gabapentin	%	Granisetron	%
Underweight (≤ 18.49)	0	0.00	0	0.00
Normal (18.50 to 24.99)	15	50.00	17	56.67
Overweight (25 to 29.99)	15	50.00	13	43.33
Obese	0	0.00	0	0.00
Total	30	100	30	100

BMI Distribution	Gabapentin	Granisetron
N	30	30
Mean	24.17	24.10
SD	1.49	1.83
P value Unpaired t Test		0.8774

Majority of the Gabapentin group patients belonged to the normal BMI class interval (n=15, 50%) with a mean BMI of 24.17. In the Granisetron group patients, majority belonged to the same BMI class interval (n=17, 56.67%) with a mean BMI of 24.10. The association between the intervention groups and BMI distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

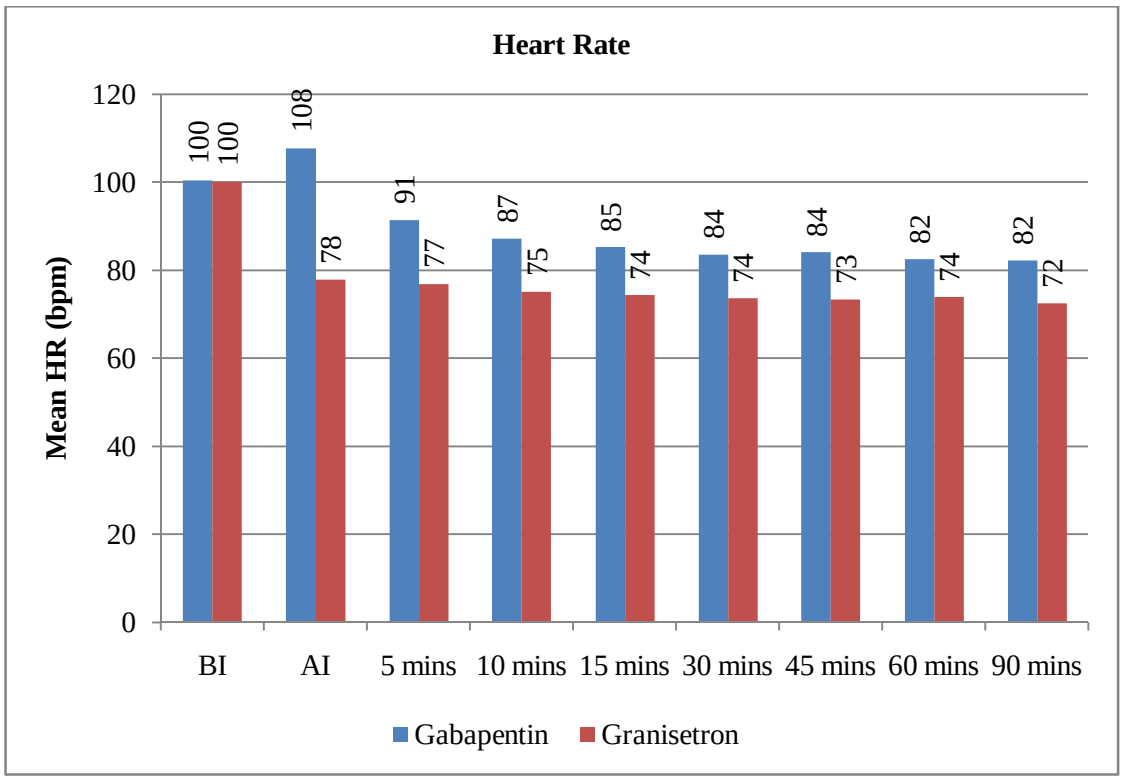
ASA Physical Classification



ASA Physical Classification	Gabapentin	%	Granisetron	%
ASA 1	13	43.33	16	53.33
ASA 2	17	56.67	14	46.67
Total	30	100	30	100
P value Chi Squared Test			0.8812	

Majority of the Gabapentin group patients belonged to the ASA 2 class interval (n=17, 56.67%). In the Granisetron group patients, majority belonged to the ASA 1 class interval (n=16, 53.33%). The association between the intervention groups and ASA Physical Classification is considered to be not statistically significant since $p > 0.05$ as per chi squared test

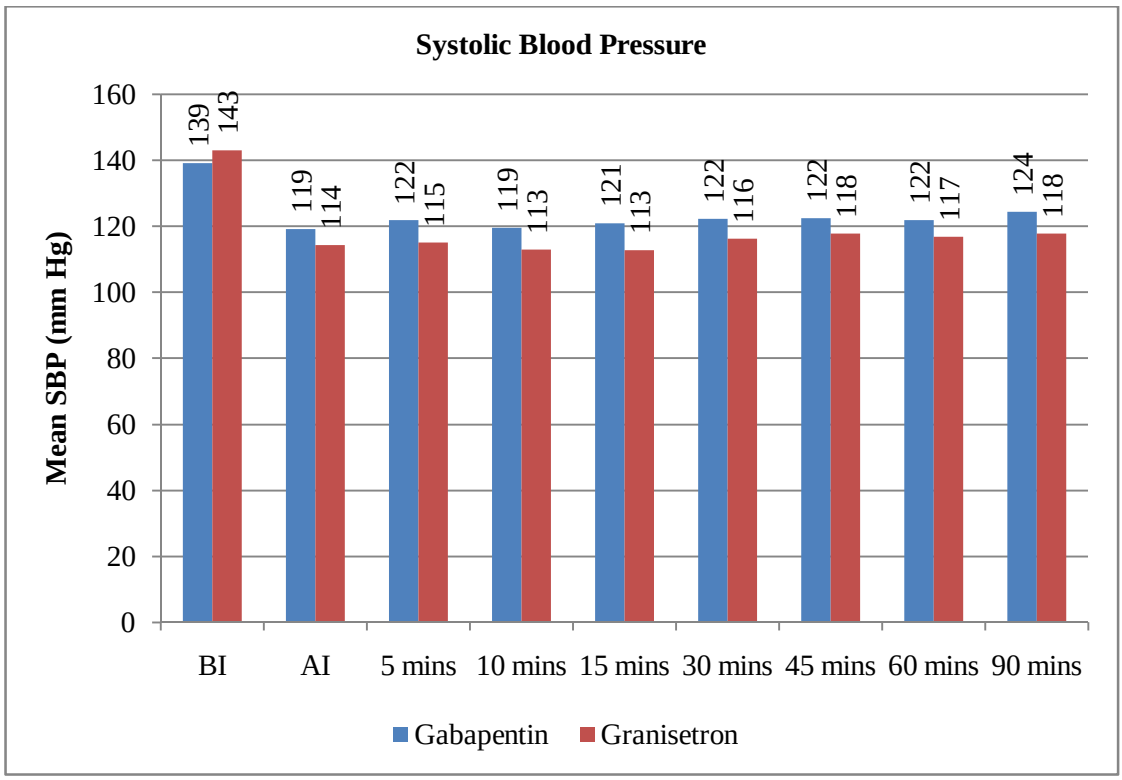
Heart Rate



Heart Rate		BI	AI	5 mins	10 mins	15 mins	30 mins	45 mins	60 mins	90 mins
Gabapentin	N	30	30	30	30	30	30	30	30	27
	Mean	100.37	107.67	91.37	87.07	85.23	83.50	84.03	82.40	82.11
	SD	13.43	12.60	14.21	13.05	14.04	15.27	15.57	15.76	14.71
Granisetron	N	30	30	30	30	30	30	30	30	30
	Mean	100.07	77.80	76.87	75.03	74.30	73.57	73.30	73.83	72.40
	SD	11.81	8.66	10.01	8.50	8.07	8.62	8.85	9.89	8.60
P values Unpaired t Test		0.9271	0.4171	0.5057	0.3491	0.3067	0.2206	0.1412	0.1468	0.2063

Majority of the Gabapentin group patients belonged had a before-after induction and intraoperatively mean heart rate of 89.30 bpm with a mean range of 82-108 bpm. In the Granisetron group patients had a mean heart rate of 77.46 bpm with a mean range of 72-100 bpm. The association between the intervention groups and heart rate before-after induction and intraoperatively is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

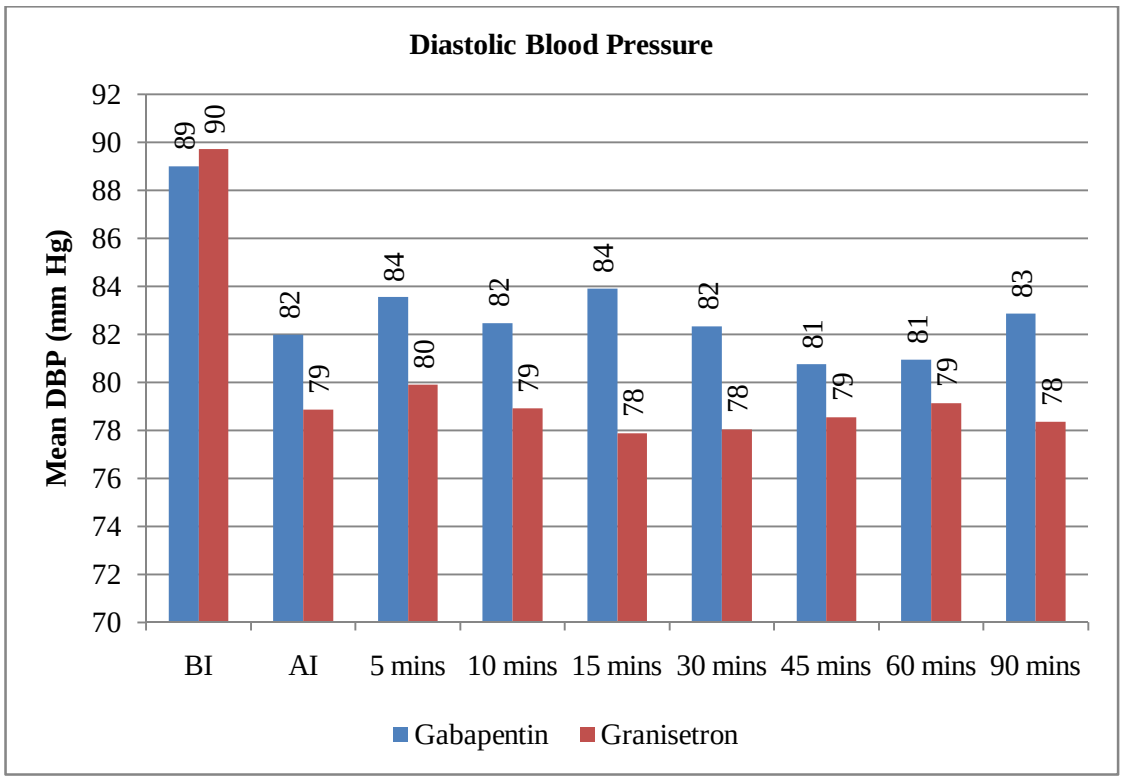
Systolic Blood Pressure



Systolic Blood Pressure		BI	AI	5 mins	10 mins	15 mins	30 mins	45 mins	60 mins	90 mins
Gabapentin	N	30	30	30	30	30	30	30	30	27
	Mean	139.10	119.00	121.70	119.47	120.90	122.13	122.37	121.83	124.22
	SD	17.03	15.83	17.89	16.47	17.65	14.74	11.87	11.23	12.97
Granisetron	N	30	30	30	30	30	30	30	30	30
	Mean	142.93	114.30	115.03	112.83	112.73	116.13	117.63	116.77	117.77
	SD	10.03	8.69	7.36	9.43	9.51	8.59	8.86	8.97	9.10
P values Unpaired t Test		0.1361	0.1768	0.1490	0.1447	0.1486	0.0132	0.0108	0.0980	0.1754

Majority of the Gabapentin group patients belonged had a before-after induction and intraoperatively mean SBP of 123.41 mm Hg with a mean range of 119-139 mm hg. In the Granisetron group patients had a mean SBP of 118.46 mm Hg with a mean range of 114-143 mm Hg. The association between the intervention groups and systolic blood pressure before-after induction and intraoperatively is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

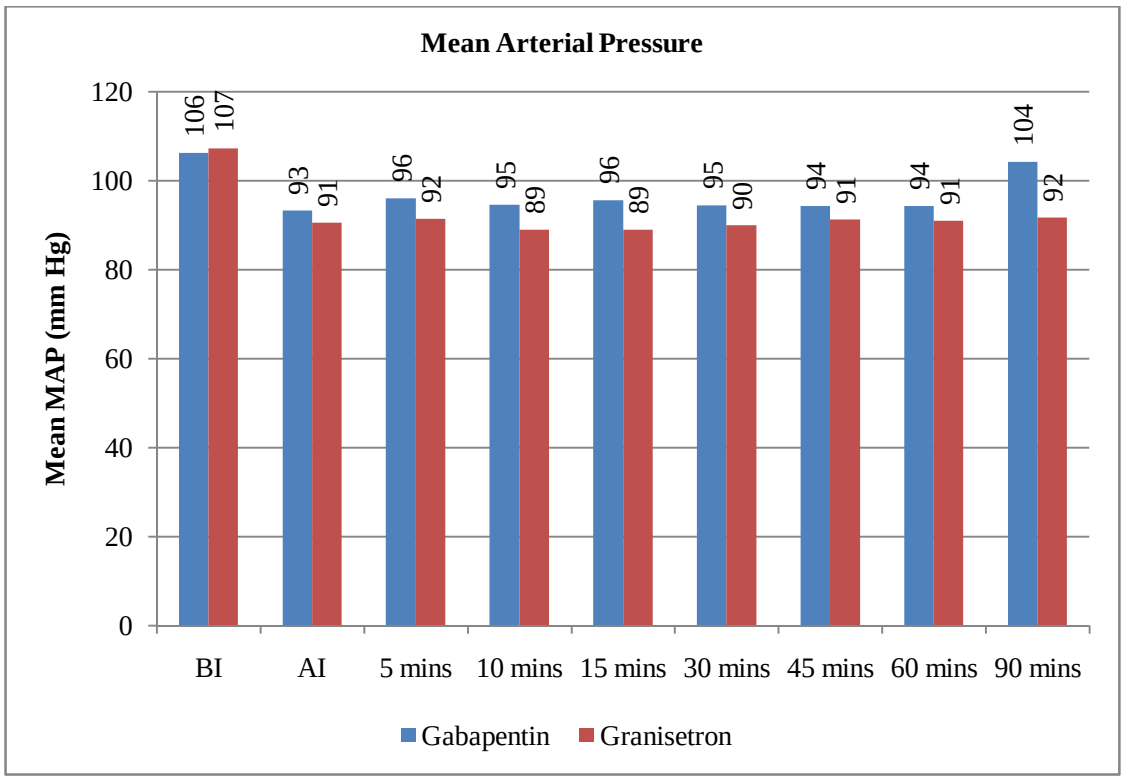
Diastolic Blood Pressure



Diastolic Blood Pressure		BI	AI	5 mins	10 mins	15 mins	30 mins	45 mins	60 mins	90 mins
Gabapentin	N	30	30	30	30	30	30	30	30	27
	Mean	89.00	81.97	83.53	82.47	83.90	82.33	80.73	80.93	82.85
	SD	8.73	11.90	14.37	13.40	14.29	10.35	8.63	8.17	9.72
Granisetron	N	30	30	30	30	30	30	30	30	30
	Mean	89.70	78.87	79.90	78.90	77.87	78.03	78.53	79.13	78.33
	SD	7.97	7.17	7.70	7.79	8.16	8.92	8.80	7.07	8.94
P values Unpaired t Test		0.7470	0.2276	0.2286	0.2138	0.0505	0.0901	0.3321	0.3654	0.0744

Majority of the Gabapentin group patients belonged had a before-after induction and intraoperatively mean DBP of 83.08 mm Hg with a mean range of 81-89 mm hg. In the Granisetron group patients had a mean SBP of 79.92 mm Hg with a mean range of 78-90 mm Hg. The association between the intervention groups and diastolic blood pressure before-after induction and intraoperatively is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

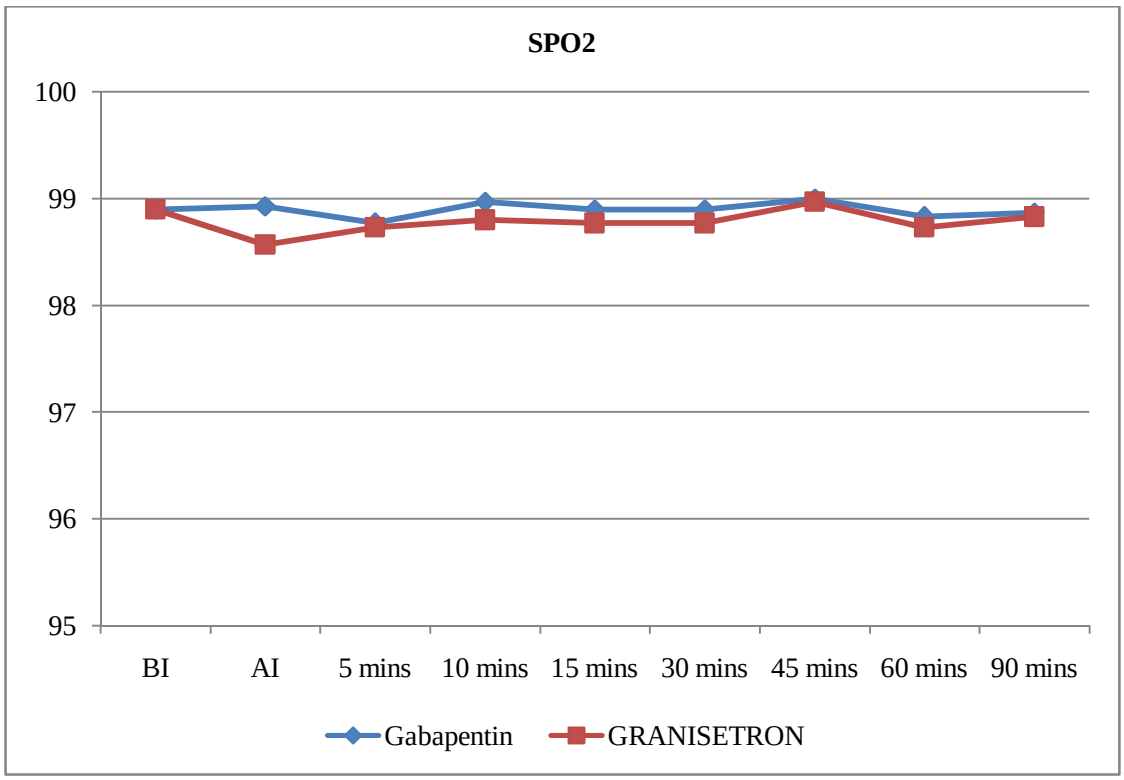
Mean Arterial Pressure



Mean Arterial Pressure		BI	AI	5 mins	10 mins	15 mins	30 mins	45 mins	60 mins	90 mins
Gabapentin	N	30	30	30	30	30	30	30	30	28
	Mean	106.37	93.43	96.13	94.67	95.73	94.60	94.40	94.33	104.32
	SD	9.90	12.58	15.36	14.47	15.32	12.13	9.82	8.83	59.97
Granisetron	N	30	30	30	30	30	30	30	30	30
	Mean	107.33	90.63	91.50	89.10	89.07	90.00	91.30	91.07	91.80
	SD	7.99	7.85	8.11	8.62	8.70	9.20	8.77	7.28	7.55
P values Unpaired t Test		0.6790	0.3063	0.1511	0.0766	0.0439	0.1038	0.2023	0.1236	0.2822

Majority of the Gabapentin group patients belonged had a before-after induction and intraoperatively mean MAPof 97.11 mm Hg with a mean range of 93-106 mm hg. In the Granisetron group patients had a mean SBP of 92.42 mm Hg with a mean range of 89-107 mm Hg. The association between the intervention groups and mean arterial pressure before-after induction and intraoperatively is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

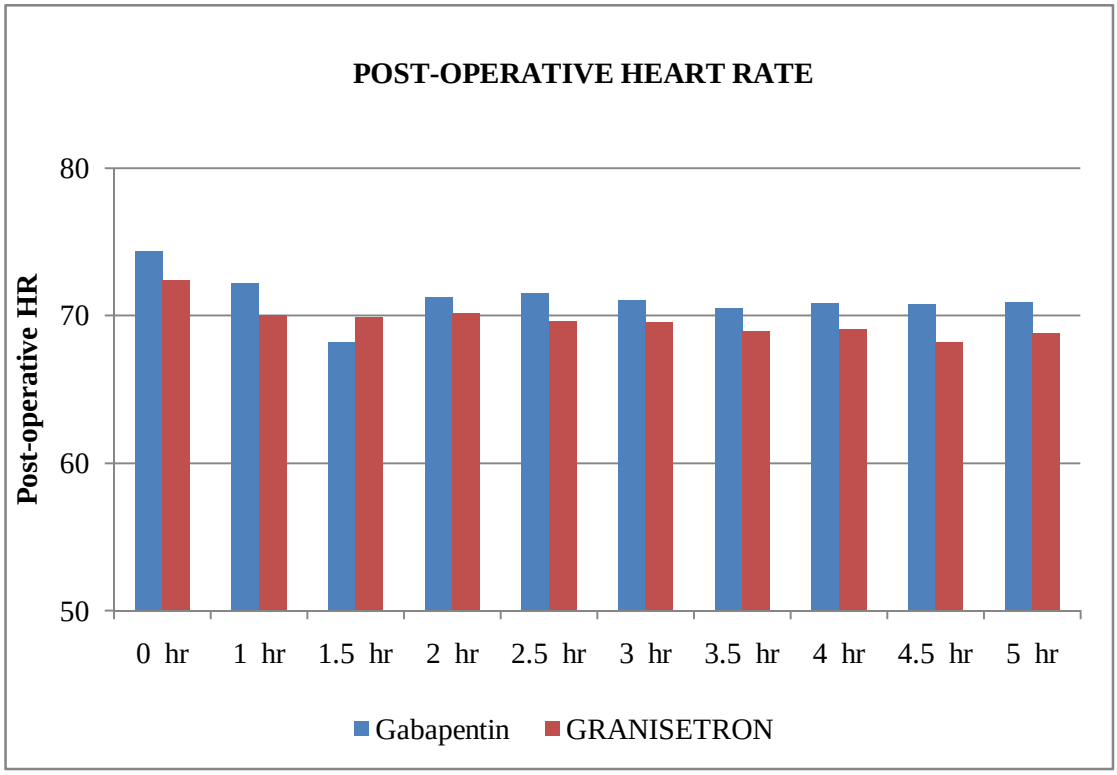
Oxygen Saturation (SPO_2)



Peripheral Capillary Oxygen Saturation		BI	AI	5 mins	10 mins	15 mins	30 mins	45 mins	60 mins	90 mins
Gabapentin	N	30	30	30	30	30	30	30	30	30
	Mean	98.90	98.93	98.77	98.97	98.90	98.90	99.00	98.83	98.87
	SD	0.31	0.25	0.43	0.18	0.31	0.31	0.00	0.38	0.35
Granisetron	N	30	30	30	30	30	30	30	30	30
	Mean	98.90	98.57	98.73	98.80	98.77	98.77	98.97	98.73	98.83
	SD	0.31	0.50	0.45	0.41	0.43	0.43	0.18	0.45	0.38
P values Unpaired t Test		1.0000	0.1122	0.7703	0.2472	0.1720	0.1720	0.3256	0.3557	0.7232

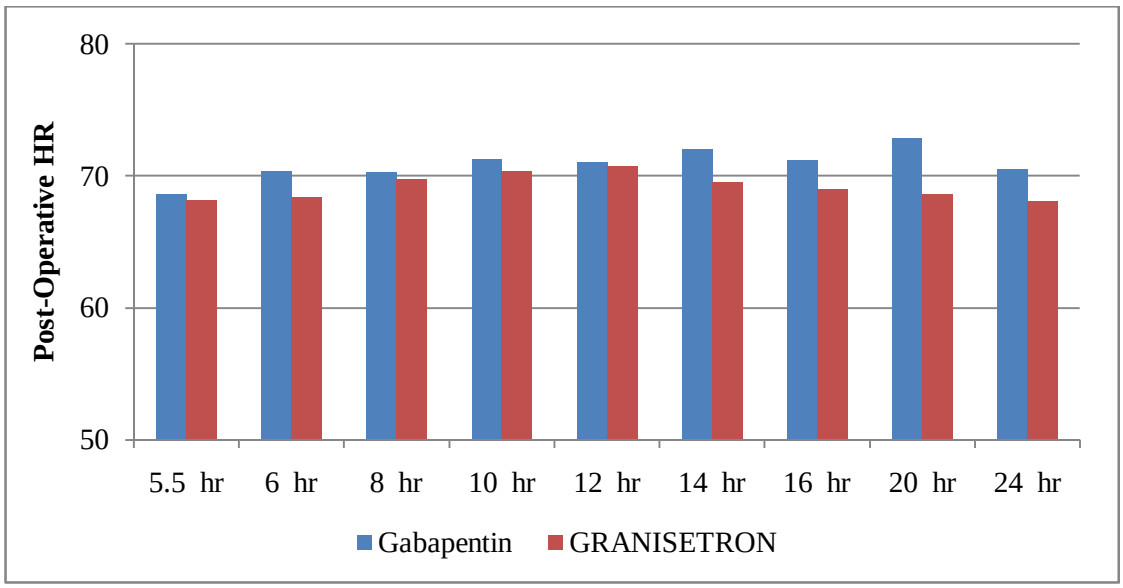
Majority of the Gabapentin group patients belonged had a mean before-after induction and intraoperatively SPO2of 98.90 % with a mean range of 98-99 %. In the Granisetron group patients had a mean SPO2of 98.79 % with a mean range of 98-99 %.. The association between the intervention groups and peripheral capillary oxygen saturation before-after induction and intraoperatively is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

Heart Rate



Heart Rate - Postoperative		0 hr	1 hr	1.5 hr	2 hr	2.5 hr	3 hr	3.5 hr	4 hr	4.5 hr	5 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30	30
	Mean	74.37	72.17	68.23	71.20	71.50	71.03	70.47	70.83	70.73	70.90
	SD	9.07	8.65	7.78	7.75	7.46	8.58	7.19	6.69	7.23	8.62
Granisetron	N	30	30	30	30	30	30	30	30	30	30
	Mean	72.40	70.03	69.90	70.13	69.63	69.53	68.93	69.07	68.17	68.80
	SD	8.60	7.28	8.12	7.51	7.39	7.37	8.41	7.02	7.33	7.50
P values Unpaired t Test		0.07	0.06	0.07	0.07	0.07	0.06	0.08	0.08	0.08	0.08

POST-OPERATIVE HEART RATE



Heart Rate - Postoperative		5.5 hr	6 hr	8 hr	10 hr	12 hr	14 hr	16 hr	20 hr	24 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30
	Mean	68.60	70.37	70.30	71.27	71.03	71.97	71.23	72.87	70.53
	SD	9.13	8.83	7.68	7.52	7.17	7.48	6.36	7.15	7.21
Granisetron	N	30	30	30	30	30	30	30	30	30
	Mean	68.13	68.37	69.73	70.37	70.73	69.57	69.00	68.63	68.10
	SD	6.65	6.68	7.18	8.91	7.51	6.54	7.35	7.13	6.47
P values Unpaired t Test		0.07	0.07	0.08	0.08	0.07	0.08	0.07	0.08	0.07

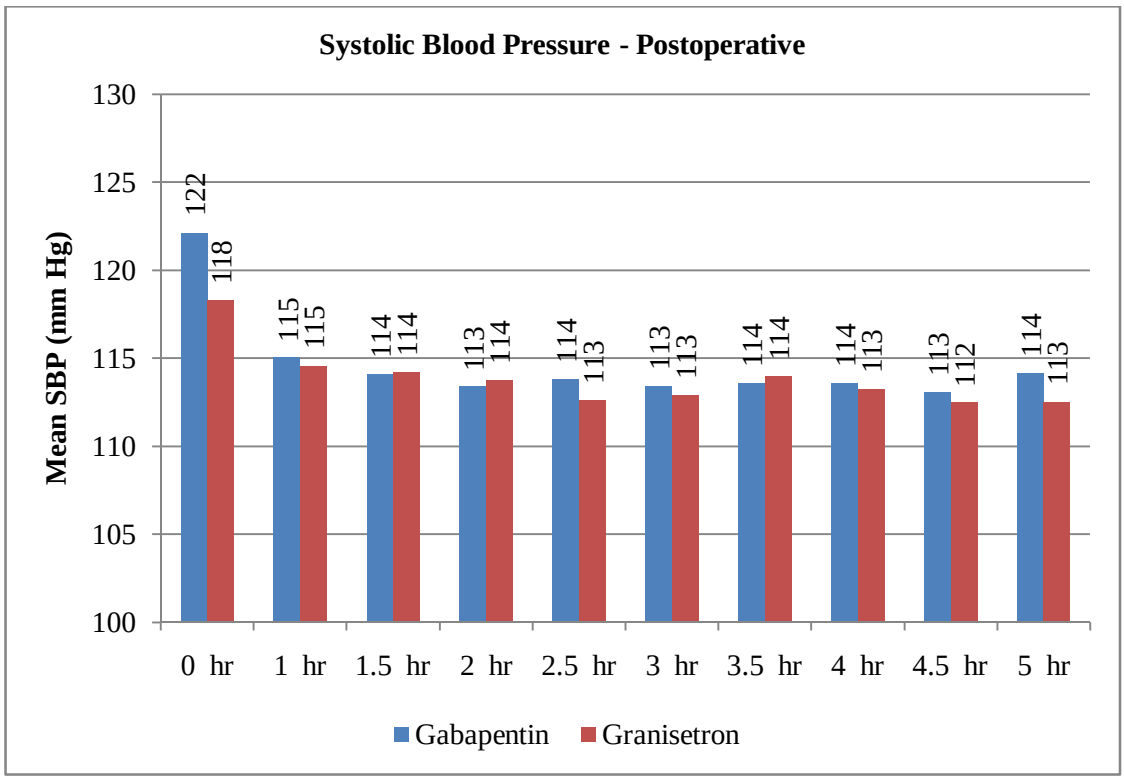
Results

By conventional criteria the association between the intervention groups and heart rate postoperatively is considered to be statistically insignificant since $p > 0.05$ as per unpaired test

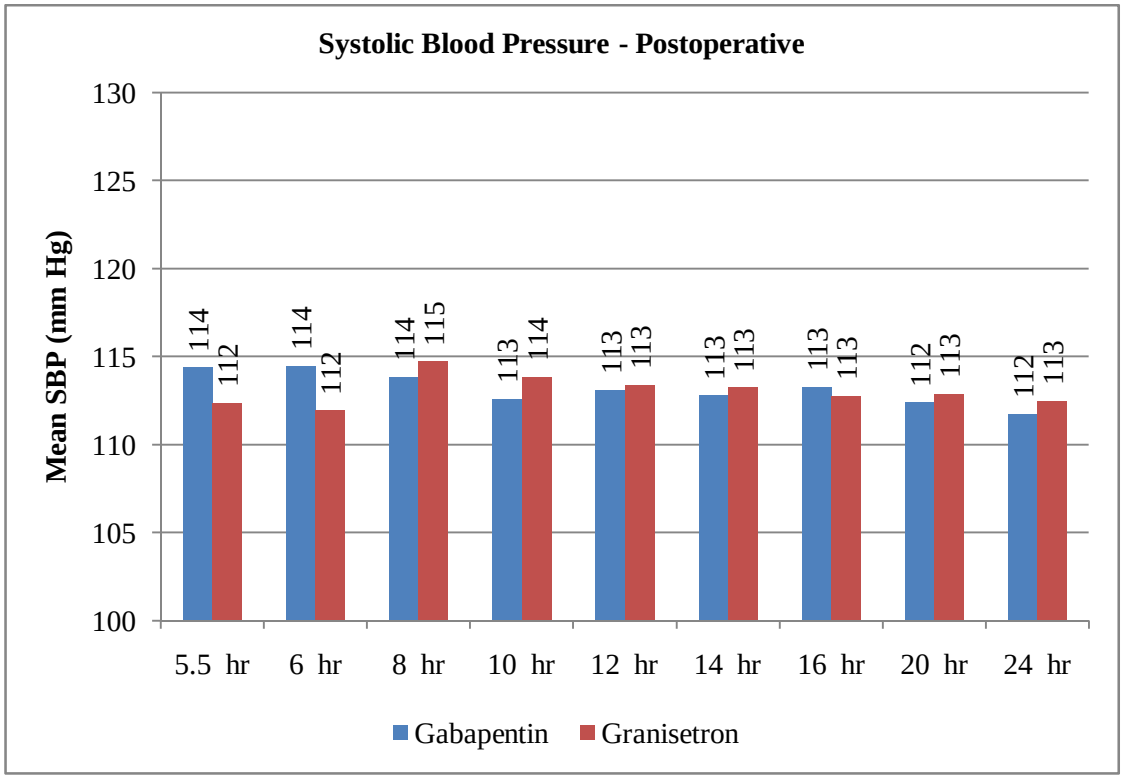
Conclusion

In this study we can safely conclude that there is no significant difference in post operative heart rate between Gabapentin and Granisetron group.

Systolic Blood Pressure



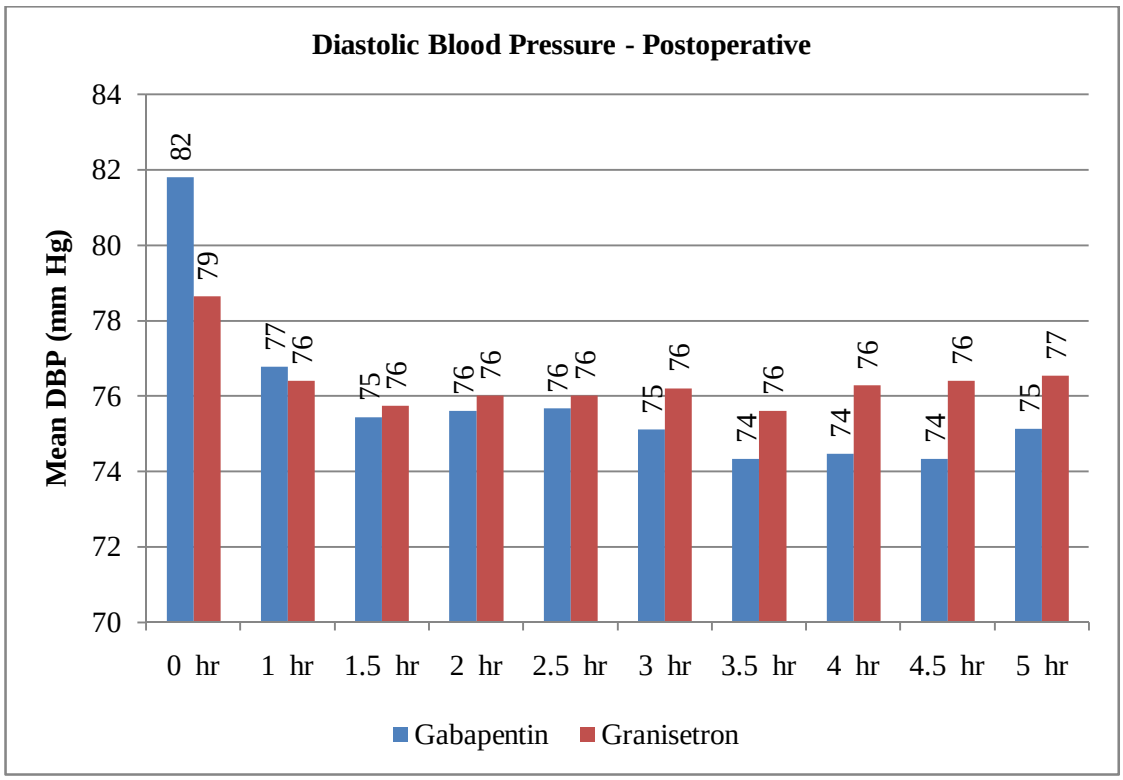
Systolic Blood Pressure - Postoperative		0 hr	1 hr	1.5 hr	2 hr	2.5 hr	3 hr	3.5 hr	4 hr	4.5 hr	5 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30	30
	Mean	122.13	115.03	114.07	113.40	113.83	113.43	113.57	113.57	113.07	114.13
	SD	8.04	6.57	5.78	6.44	7.02	7.21	6.52	6.73	6.14	6.96
Granisetron	N	30	30	30	30	30	30	30	30	30	30
	Mean	118.30	114.57	114.20	113.73	112.63	112.90	113.97	113.23	112.47	112.53
	SD	8.61	7.04	6.41	6.21	6.71	6.91	7.39	6.82	6.96	7.24
P values Unpaired t Test		0.0800	0.7917	0.9328	0.8389	0.5012	0.7710	0.8249	0.8496	0.7245	0.3865



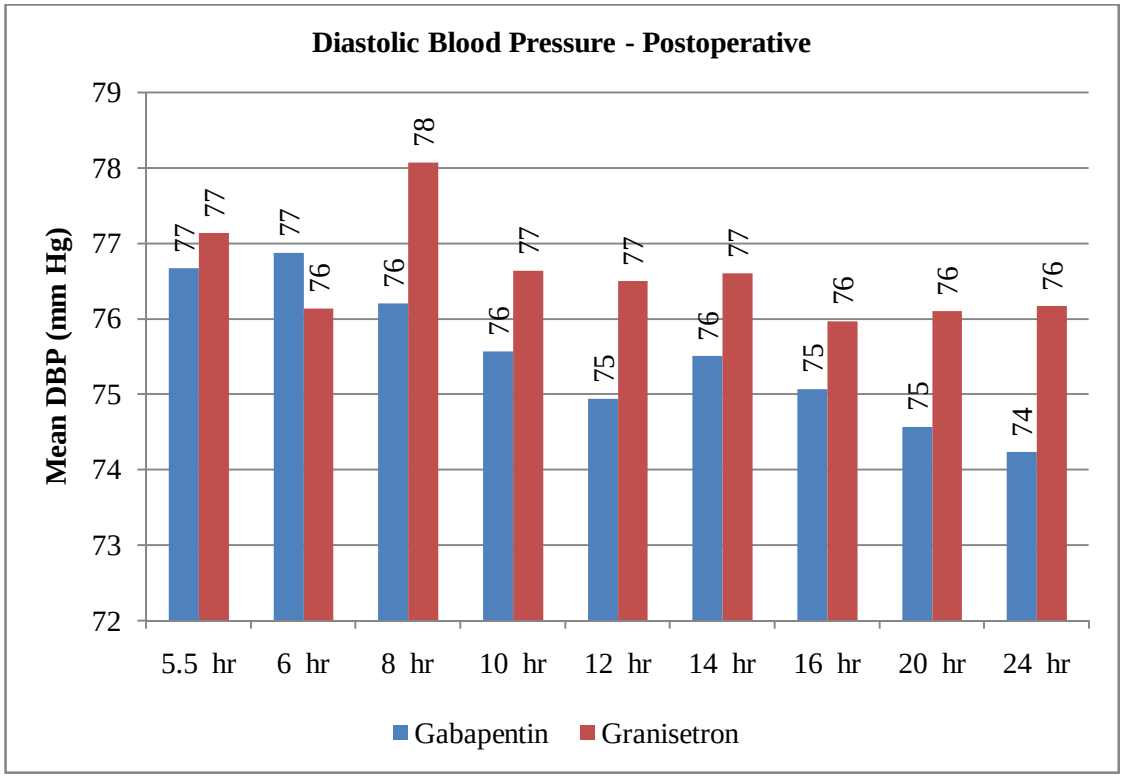
Systolic Blood Pressure - Postoperative		5.5 hr	6 hr	8 hr	10 hr	12 hr	14 hr	16 hr	20 hr	24 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30
	Mean	114.37	114.47	113.83	112.60	113.10	112.80	113.27	112.40	111.73
	SD	8.80	8.25	8.17	8.43	8.22	7.53	7.63	7.10	6.52
Granisetron	N	30	30	30	30	30	30	30	30	30
	Mean	112.37	111.93	114.73	113.83	113.37	113.23	112.77	112.90	112.50
	SD	6.56	6.65	8.79	7.12	6.02	5.63	6.16	5.79	5.33
P values Unpaired t Test		0.3226	0.1958	0.6827	0.5428	0.8866	0.8017	0.7812	0.7661	0.6199

Majority of the Gabapentin group patients belonged had a mean postoperative SBP of 113.94 mm Hg with a mean range of 112-115 mm hg. In the Granisetron group patients had a mean SBP of 113.48 mm Hg with a mean range of 112-118 mm Hg. The association between the intervention groups and postoperative systolic blood pressure is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

Diastolic Blood Pressure



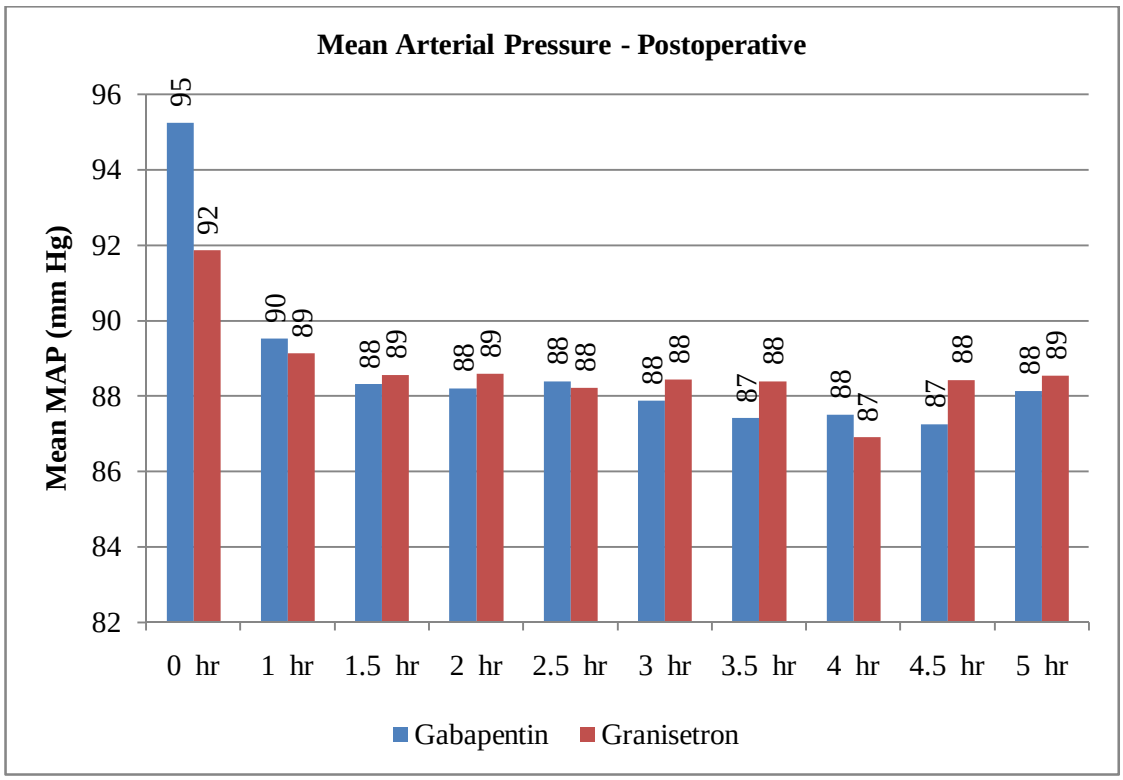
Diastolic Blood Pressure - Postoperative		0 hr	1 hr	1.5 hr	2 hr	2.5 hr	3 hr	3.5 hr	4 hr	4.5 hr	5 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30	30
	Mean	81.80	76.77	75.43	75.60	75.67	75.10	74.33	74.47	74.33	75.13
	SD	8.97	7.31	7.06	6.98	7.32	7.00	6.70	6.64	6.69	7.23
Granisetron	N	30	30	30	30	30	30	30	29	30	30
	Mean	78.63	76.40	75.73	76.00	76.00	76.20	75.60	76.28	76.40	76.53
	SD	8.98	7.32	7.32	7.41	7.43	7.12	7.48	7.61	7.34	7.17
P values Unpaired t Test		0.177	0.85	0.88	0.83	0.86	0.55	0.49	0.33	0.26	0.45



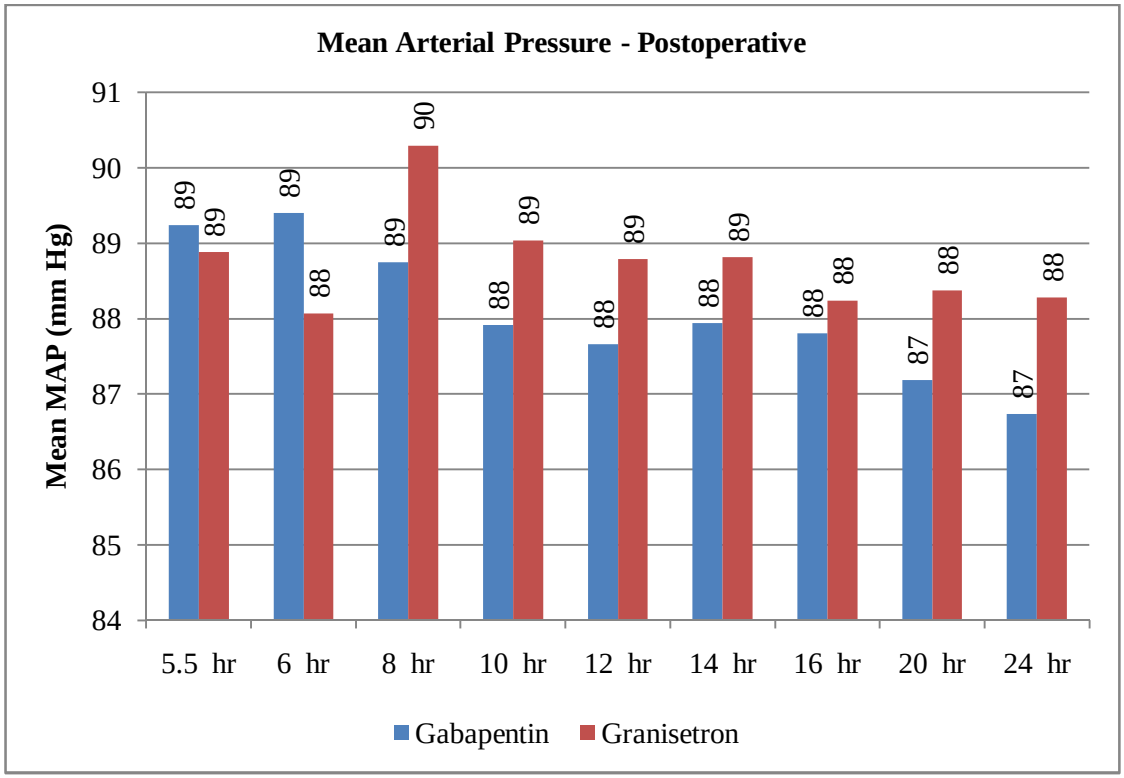
Diastolic Blood Pressure - Postoperative		5.5 hr	6 hr	8 hr	10 hr	12 hr	14 hr	16 hr	20 hr	24 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30
	Mean	76.67	76.87	76.20	75.57	74.93	75.50	75.07	74.57	74.23
	SD	8.00	7.80	5.98	5.61	6.25	8.03	8.03	6.74	5.68
Granisetron	N	30	30	30	30	30	30	30	30	30
	Mean	77.13	76.13	78.07	76.63	76.50	76.60	75.97	76.10	76.17
	SD	7.69	7.67	9.10	7.82	7.70	7.24	8.89	8.55	8.77
P values Unpaired t Test		0.8186	0.7148	0.3524	0.5463	0.3907	0.5797	0.6821	0.4438	0.3159

Majority of the Gabapentin group patients belonged had a mean postoperative DBP of 75.70 mm Hg with a mean range of 74-82 mm hg. In the Granisetron group patients had a mean DBP of 76.48 mm Hg with a mean range of 76-79 mm Hg. The association between the intervention groups and postoperative diastolic blood pressure is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

Mean Arterial Pressure



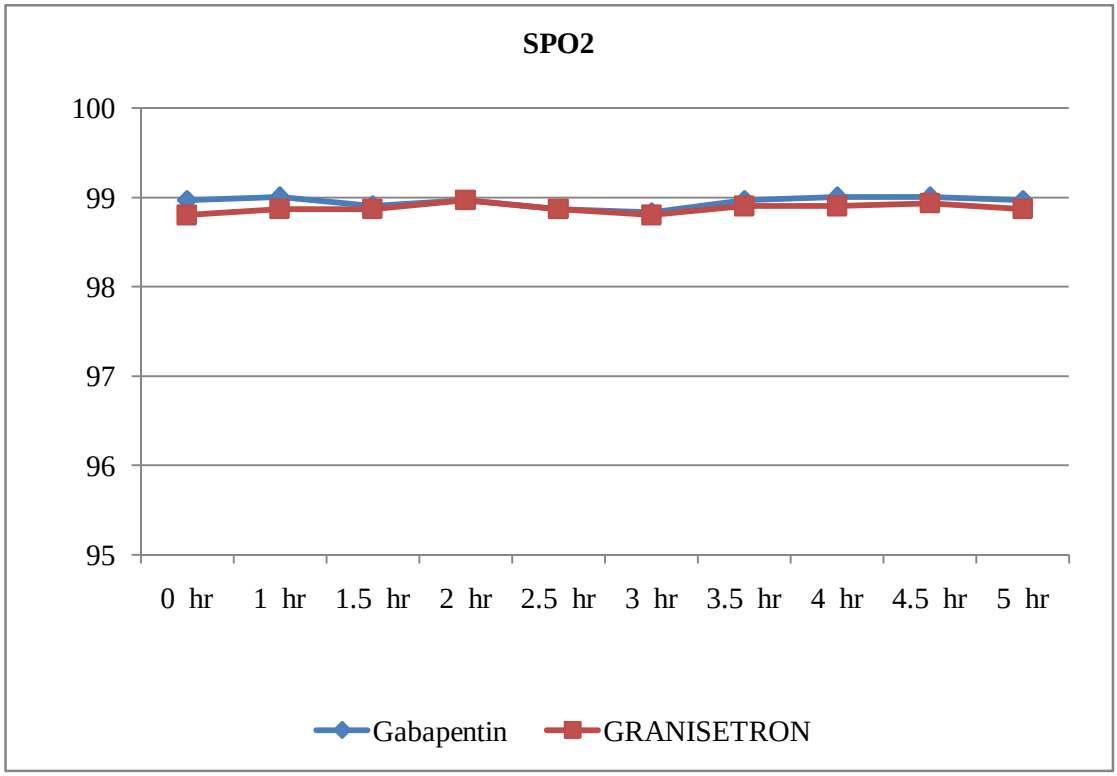
Mean Arterial Pressure - Postoperative		0 hr	1 hr	1.5 hr	2 hr	2.5 hr	3 hr	3.5 hr	4 hr	4.5 hr	5 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30	30
	Mean	95.24	89.52	88.31	88.20	88.39	87.88	87.41	87.50	87.24	88.13
	SD	6.23	5.08	4.73	4.76	4.85	4.74	4.40	3.83	4.23	5.50
Granisetron	N	30	30	30	30	30	30	30	30	30	30
	Mean	91.86	89.12	88.56	88.58	88.21	88.43	88.39	86.90	88.42	88.53
	SD	7.60	5.87	5.91	5.85	5.94	5.49	5.94	11.08	5.42	5.71
P values Unpaired t Test		0.064	0.778	0.860	0.785	0.899	0.677	0.472	0.781	0.352	0.783



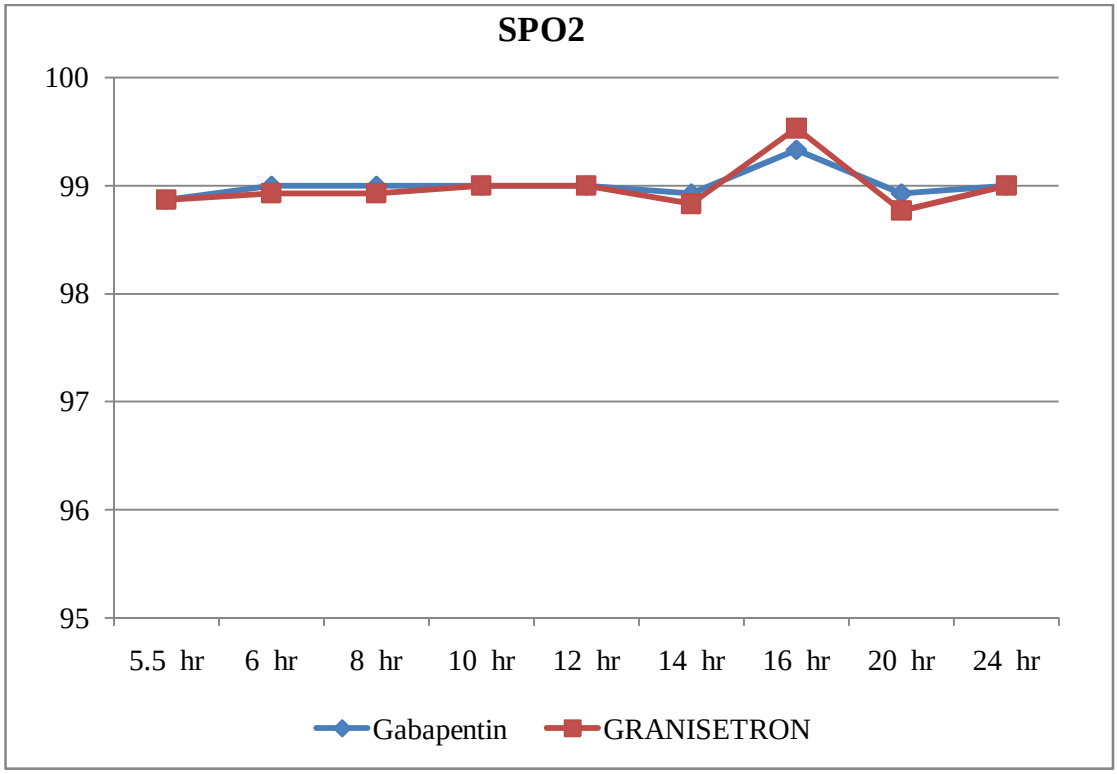
Mean Arterial Pressure - Postoperative		5.5 hr	6 hr	8 hr	10 hr	12 hr	14 hr	16 hr	20 hr	24 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30
	Mean	89.23	89.40	88.74	87.91	87.66	87.93	87.80	87.18	86.73
	SD	6.78	6.94	5.31	4.98	4.87	6.20	6.43	5.33	4.90
Granisetron	N	30	30	30	30	30	30	30	30	30
	Mean	88.88	88.07	90.29	89.03	88.79	88.81	88.23	88.37	88.28
	SD	6.06	6.15	7.83	5.79	5.78	5.03	6.24	6.17	6.02
P values Unpaired t Test		0.8312	0.4344	0.3754	0.4240	0.4152	0.5494	0.7920	0.4275	0.2806

Majority of the Gabapentin group patients belonged had a mean postoperative MAP of 88.44 mm Hg with a mean range of 87-95 mm hg. In the Granisetron group patients had a mean MAP of 88.72 mm Hg with a mean range of 87-92 mm Hg. The association between the intervention groups and postoperative mean arterial pressure is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

SPO_2



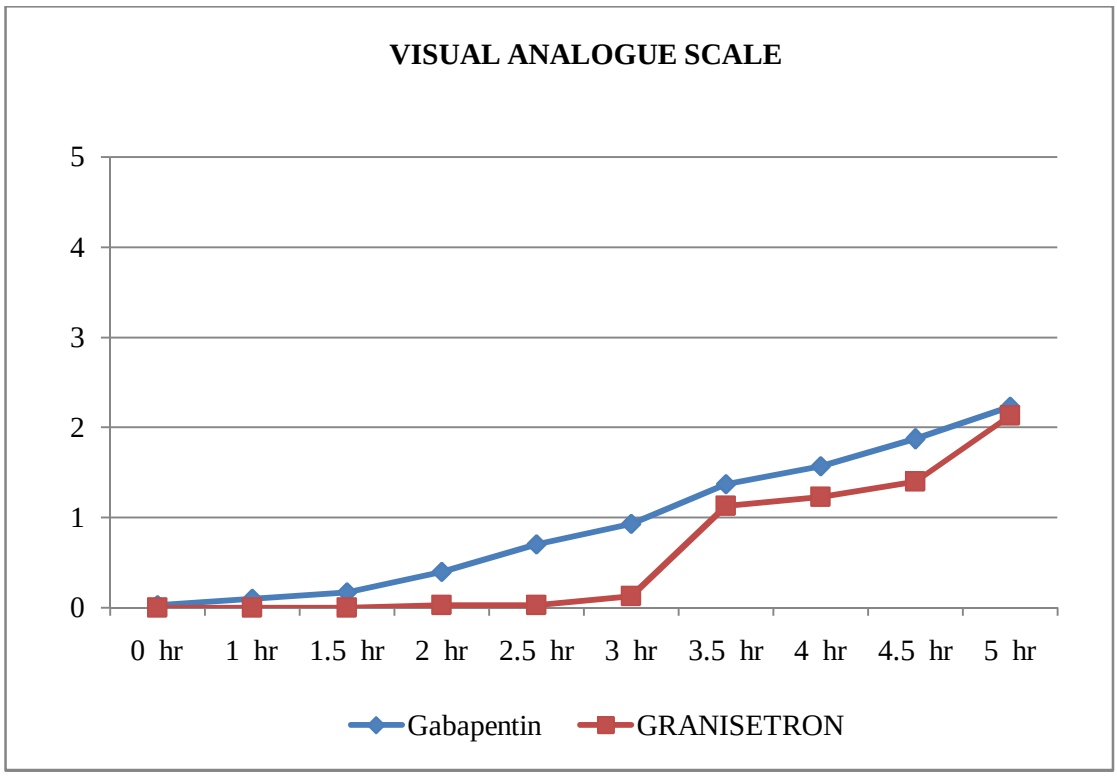
SPO_2 Postoperative		0 hr	1 hr	1.5 hr	2 hr	2.5 hr	3 hr	3.5 hr	4 hr	4.5 hr	5 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30	30
	Mean	98.97	99.00	98.90	98.97	98.87	98.83	98.97	99.00	99.00	98.97
	SD	0.18	0.00	0.31	0.18	0.35	0.38	0.18	0.00	0.00	0.18
Granisetron	N	30	30	30	30	30	30	30	30	30	30
	Mean	98.80	98.87	98.87	98.97	98.87	98.80	98.90	98.90	98.93	98.87
	SD	0.41	0.35	0.35	0.18	0.35	0.41	0.31	0.31	0.25	0.35
P values Unpaired t Test		0.347	0.443	0.694	1.000	1.000	0.744	0.30	0.083	0.161	0.169



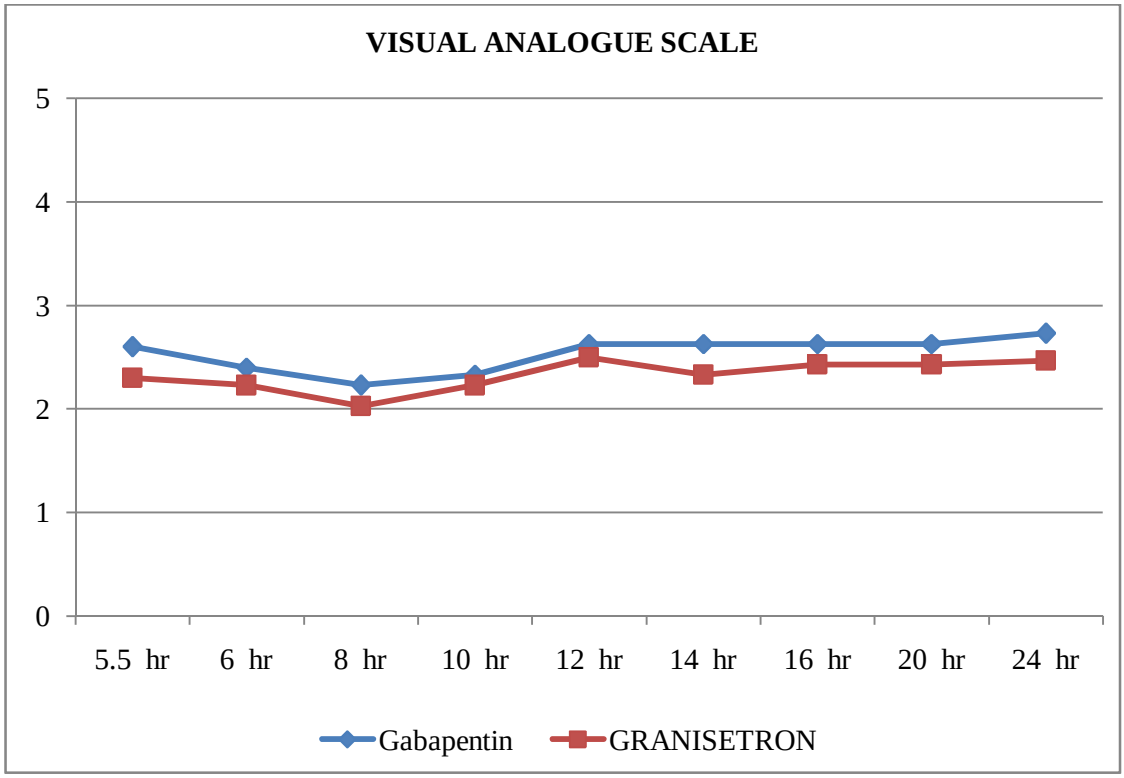
SPO_2		5.5 hr	6 hr	8 hr	10 hr	12 hr	14 hr	16 hr	20 hr	24 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30
	Mean	98.87	99.00	99.00	99.00	99.00	98.93	99.53	98.93	99.00
	SD	0.35	0.00	0.00	0.00	0.00	0.25	0.33	0.25	0.00
Granisetron	N	30	30	30	30	30	30	30	30	30
	Mean	98.87	98.93	98.93	99.00	99.00	98.83	98.53	98.77	99.00
	SD	0.35	0.25	0.25	0.00	0.00	0.38	0.33	0.43	0.00
P values Unpaired t Test		1.0000	0.1608	0.1608	1.0000	1.0000	0.2354	1.0000	0.0739	1.0000

Majority of the Gabapentin group patients belonged had a mean postoperative SPO_2 of 98% with a mean range of 98-99 %. In the Granisetron group patients had a mean SPO_2 of 99% with a mean range of 99-100 %. The association between the intervention groups and postoperative peripheral capillary oxygen saturation is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

Visual Analogue Scale



Visual Analogue Score - Postoperative		0 hr	1 hr	1.5 hr	2 hr	2.5 hr	3 hr	3.5 hr	4 hr	4.5 hr	5 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30	30
	Mean	0.03	0.10	0.17	0.40	0.70	0.93	1.37	1.57	1.87	2.23
	SD	0.18	0.31	0.38	0.50	0.60	0.64	0.61	0.73	0.86	1.01
Granisetron	N	30	30	30	30	30	30	30	30	30	30
	Mean	0.00	0.00	0.00	0.03	0.03	0.13	1.13	1.23	1.40	2.13
	SD	0.00	0.00	0.00	0.18	0.18	0.35	0.35	0.50	0.62	0.63
P values Unpaired t Test		0.3256	0.0831	0.0226	0.06	0.07	0.07	0.08	0.07	0.08	0.09



Visual Analogue Score - Postoperative		5.5 hr	6 hr	8 hr	10 hr	12 hr	14 hr	16 hr	20 hr	24 hr
Gabapentin	N	30	30	30	30	30	30	30	30	30
	Mean	2.60	2.40	2.23	2.33	2.63	2.63	2.63	2.63	2.73
	SD	1.16	1.30	1.28	1.35	1.54	1.65	1.67	1.63	1.57
Granisetron	N	30	30	30	30	30	30	30	30	30
	Mean	2.30	2.23	2.03	2.23	2.50	2.33	2.43	2.43	2.47
	SD	0.72	0.75	0.97	1.10	0.65	0.66	0.68	0.83	0.85
P values Unpaired t Test		0.07	0.08	0.07	0.08	0.07	0.08	0.08	0.099	0.0834

Results

By conventional criteria the association between the intervention groups and visual analogue score postoperatively is considered to be statistically insignificant since $p > 0.05$ as per unpaired t test.

DISCUSSION

The optimal anti – emetic regimen for post-operative nausea and vomiting (PONV) is one which would decrease the incidence of nausea and vomiting without increasing the risk of unacceptable side effects like sedation , extrapyramidal symptoms , dry mouth , hypotension etc. Inspite of much attention paid to Post Operative Nausea and Vomiting the optimal anti-emetic regimen in surgical setting has still has not been established.

Gabapentin is an anti-convulsant drug used to treat partial seizure and neuropathic pain. Recently , it has been found that , it has an anti-emetic properties.

The observation and results revealed that there is no significant difference between Graniseton group and Gabapentin group in preventing post operative nausea and vomiting. This is manifested as similar Visual Analogue Scale (VAS) and intraoperative and post operativehaemodynamics. These findings are similar to results previously published studies and meta analysis of randomized controlled studies comparing these two drugs.

DEMOGRAPHIC PROFILE :

This present study included the patient posted for middle ear surgery. The demographic profile of our patients was comparable in both the groups with the respect to age, BMI, ASA Physical status. There is no difference in the duration of surgery among the two groups.

INTRAOPERATIVE PERIOD

HAEMODYNAMICS

A study done by Morteza Heidari, Azim Honarmand et al compared Granisetron and Gabapentin in preventing post operative nausea and vomiting after middle ear surgery in adults. Both group of patient intraoperative vitals were recorded. There is no significant difference in intra operative vitals between the two groups.

The present study also revealed that there is no significant difference in intra operative vitals between the Granisetron and Gabapentin groups.

POST OPERATIVE PERIOD

Visual Analogue Scale

A study done by MortezaHeidari, Azim Honarm and et al compared Granisetron and Gabapentin group. The severity of nausea was assessed by using Visual Analogue Score. Results showed that there is no significant difference between the two groups with respect to Visual Analogue Scale (VAS).

The present study also assessed the Visual Analogue Scale (VAS) post operatively for 24 hrs. It revealed that there is no significant difference in Visual Analogue Scale (VAS) for vomiting between the Granisetron and Gabapentin group. This result is similar to the study done previously.

HEART RATE

A study done by Morteza Heidari, Azim Honarm and et al compared Granisetron and Gabapentin group with respect to post-operative heart rate . The result showed that there is no significant difference in post-operative heart rate between the two groups.

The present study also assessed the post-operative heart rate for 24 hrs. it revealed that there is no significant difference in HR post operatively between the Granisetron and Gabapentin group. This result correlates with the study done previously.

SYSTOLIC BLOOD PRESSURE

A study done by Morteza Heidari, Azim Honarm and et al compared Granisetron and Gabapentin group with respect to post-operative systolic blood pressure. The result showed that there is no significant difference in post-operative systolic blood pressure between the two groups.

The present study also assessed the post-operative Systolic Blood Pressure (SBP) for 24 hrs. it revealed that there is no significant difference in Systolic Blood Pressure (SBP) post operatively between the Granisetron and Gabapentin group. This result correlates with the study done previously.

DIASTOLIC BLOOD PRESSURE

A study done by MortezaHeidari,AzimHonarmand et al compared Granisetron and Gabapentin group with respect to post-operative diastolic

blood pressure . The result showed that there is no significant difference in post-operative diastolic blood pressure between the two groups.

The present study also assessed the post operative Diastolic Blood Pressure (DBP) for 24 hrs. it revealed that there is no significant difference in Diastolic Blood Pressure (DBP) post operatively between the Granisetron and Gabapentin group. This result correlates with the study done previously.

MEAN ARTERIAL PRESSURE

A study done by Morteza Heidari,Azim Honarm and et al compared Granisetron and gabapentin group with respect to post-operative mean arterial pressure. The result showed that there is no significant difference in post-operative mean arterial pressure between the two groups.

The present study also assessed the post-operative Mean Arterial Pressure (MAP) for 24 hrs. It revealed that there is no significant difference in Mean Arterial Pressure (MAP) post operatively between the Granisetron and Gabapentin group. This result correlates with the study done previously.

SUMMARY

To summarize, on conducting a double blinded randomized control study on patients undergoing middle ear surgery, it has been concluded that Granisetron and Gabapentin groups have equal anti- emetic effect. Intra operative and Post operative haemodynamics were also noted among the two groups and found to be insignificant. No incidence of side effects like respiratory depression, drowsiness, vertigo and headache noted among the both the group .

CONCLUSION

In this study we can safely conclude that Gabepentin group and Granisetron group have equal anti-emetic effects without any significant side effects and it is useful in preventing post-operative nausea and vomiting in middle ear surgeries.

BIBLIOGRAPHY

1. ApfelCC ,Kranke P et al comparison of surgical site and patient history with a simplified risk score for the prediction of post operative nausea and vomiting . Anesthesia2004 ; 59 : 1078-1082
2. Andrews P.L.R .Physiology of nausea and vomiting Br J Anesthesia1992 .
3. Ajori l et al Effect of Gabapentin on post operative pain and nausea and vomiting after abdominal hysterectomy.2012; 285 : 677-82
4. Arif AS et al. Postoperative nausea and vomiting- a review. Middle East J anaesthesia 2001;16:127-54
5. Achuthan S et al . Gabapentin prophylaxsis for post operative nausea and vomiting in abdoiminalsurgeries . 2015; 114: 588-97
6. AshutoshSayana et al . Comparative study of Metoclopromide ,Ondansetron and Granisetron in prophylaxsis of post operative nausea and vomiting in patient undergoing laproscopic cholecystectomy. 2012; 2 : 2231-4423
7. Beattie et al. Incidence of PONV is influenced by the day of menstrual cycle . Canadian Journal Anesthesia 1991 ; 38: 298—302
8. Bestas et al . Effects of Ondansetron and Granisetron on PONV in adult patient undergoing laproscopic cholecystectomy . 2007 ; 68 : 303- 312
9. Bunce K .T . The role of 5 HT in PONV Br . J Anesthsia 1992
10. Dundee JW Et al . Traditional Chinese acupuncture , a potentially useful anti –emetic Br J medical journal 1986 ; 293: 583-584
11. FirdoseShafi Sheikh et al . Comparative study of Granisetron versus combination of Granisetron with Dexamethosone in the prevention of post

operative nausea and vomiting in the patients undergoing elective plastic surgical procedures in head and neck region. 2012; 32

12. Fuji et al Granisetron and Dexamethasone combination for reducing nausea and vomiting during and after spinal anesthesia for caesarean section . 1999; 88: 1346- 50
13. Fuji et al . Comparison of Granisetron and Droperidol and Metoclopromide in the treatment of established nausea and vomiting after breast surgery. 2003;25:1142- 9
14. Gan TJ et al . Double blind comparison of Granisetron , Promethazine or A combination of both for prevention of PONV in female undergoing out patientlaproscopies. 2009 ; 56 : 829-36
15. Guyton and Hall Text book of medical physiology- 13 th edition
16. Ganong's Review of medical physiology -24th edition
17. Grabowshka-Gawe A. Postopertive nausea and vomiting – causes, prevention, treatment 2005;62:1517-20
18. Goodman and Gillman . The pharmacological basis of therapeutics -12th edition
19. Ganjare A et al. Comparative electrocardiographic effects of intravenous Ondansetron and Granisetron in patients undergoing surgery for carcinoma breast 2013;57:41-5
20. Honkavaara P et al . nausea and vomiting after gynaecological laproscopy depends up on phase of the menstrual cycle 1991 ; 38: 876-879
21. Katzung and Trevor's Basics and clinical pharmacology – 11th edition
22. Kazemi – Kjellberg F et al . Treatment of established post operative nausea and vomiting 2001 ; 1: 2

23. Khademi S etal . Effects of pre operative Gabapentin on post operative nausea and vomiting after open cholecystectomy 2010; 19: 57-60
24. KovacAL .L . Prevention and Treatment of post operative nausea and vomiting . drugs 2000; 59: 213- 243
25. Korttila A K et al . Prevention and Treatment of post operative nausea and vomiting – Studies on different anti – emetics , their combination and dosing regimens 2003 ; 26: 1- 78
26. Miller's Anesthesia – 8th edition
27. Morgan and Mikhail's Clinical Anesthesiology – 5th edition
28. MortezaHeidari et al .Granisetron versus Gabapentin in preventing post operative nausea and vomiting after middle ear surgery in adults. 2015 ; 4 : 22
29. Mohammed MH et al .Pre operative Gabapentin decreases the incidence of post operative vomiting and analgesic requirement after paediatric adenotonsillectomy. 2014; 30: 225- 8
30. NethraHN et al . A comparative study of Ondansetron and Granisetron in combination with Dexamethasone in prevention of post operative nausea and vomiting in total abdominal hysterectomy patients. 2014 ; 4 : 2249-6467
31. Papadima A et al .Granisetron versus Tropisetron in the prevention of post operative nausea and vomiting after total thyroidectomy 2013 ; 7 : 68-74
32. Pandey'sCK . et al . Prophylactic Gabapentin for prevention of post operative nausea and vomiting in patients undergoing laparoscopic choolecystectomy 2006 ; 52 : 97- 100

33. Stoelting's pharmacology and physiology – 5th edition

34. White PF et al . The use of oral Granisetron versus intravenous Ondansetron for anti – emetic prophylaxsis in patients undergoing laproscopic surgeries. 2006 ; 102 : 1387- 93

PROFORMA

TITLE:

Comparison of Granisetron vs Gabapentin in preventing postoperative nausea and vomiting after middle ear surgery in adults".

DATE: ROLL NO:

NAME: SEX :

AGE: IP NO:

ASSEMENT NO: DIAGNOSIS:

SURGICAL PROCEDURE:

PRE OP ASSESSMENT:

CVS: HT (cm) : SPO2 :

RS: WT (kg) : HR :

HISTORY : Previous PONV (Yes / No), Drug Allergy (Yes / No)

ANY CO-MORBID ILLNESS : GERD / APD (Yes / No), Smoker / Alcoholic (Yes / No)

H/O PREVIOUS SURGERIES :

INFORMED CONSENT IN TAMIL : (Yes / No)

IV LINE

PREMEDICATION

DURATION OF ANAESTHESIA : .....IN MINS INDUCTION/INTUBATION TIME :..... EXTUBATION TIME : .....

DURATION OF SURGERY.....IN MINS INCISION TIME : ..... CLOSURE TIME .....

VITALS

Time in mins	O	30	60	90	120	150
Heart Rate						
MAP						
SPO2						

POST OP

Time in hrs	O	½ hr	1 hrs	8 hrs	16 hrs	24 hrs
Heart Rate						
MAP						
SPO2						

Duration of recovery stay

Time of entry into PACU	Time of out of PACU

MEASURES OF STUDY OUTCOME

VAS SCORE IN:

Time	**Severity of Nausea & Vomiting**
Just after arrival to the Recovery Room	
30 Minutes	
8 Hours	
16 Hours	
24 Hours	

INFORMATION TO THE PARTICIPANTS

Investigator: Dr.V.Balakrishnan

Name of the Participant:

Title: **"A prospective, randomized study comparing the antiemetic effect of intravenous Granisetron and oral Gabapentin in preventing postoperative nausea and vomiting after middle ear surgery in adults"**

You are invited to take part in this research study. We have got approval from the IEC. You are asked to participate because you satisfy the eligibility criteria. We want to compare and study the safety and antiemetic effect of Gabapentin and Granisetron in preventing postoperative nausea and vomiting in patients undergoing middle ear surgeries.

What is the Purpose of the Study:

For Middle ear sureries Granisetron and Gabapentin were used as a premedication in prevention of postoperative nausea and vomiting in adults. Severity of PONV assesed by using Visual Analogue Scale (VAS).

The Study Design:

All the patients in the study will be divided into two groups.

Group 1 – patients receiving intravenous Granisetron 3mg 2 mins before induction

Group 2 – patients receiving Gabapentin 300mg orally 1hr before induction

All patients will be given general anaesthesia

BENEFITS

Middle ear surgeries are more prone for Nausea & Vomiting in the postoperative period, the use of Gabapentin & Granisetron are effective in preventing PONV.

DISCOMFORTS AND RISK:

The study poses hardly any risk as the drugs have been in use for a long time in preventing post operative nausea and vomiting and any side effects produced by these drugs will be appropriately dealt with. Patients who don’t want to be part of study may withdraw as per their wish.

PATIENT CONSENT FORM

TITLE:

Comparison of Granisetron vs Gabapentin in preventing postoperative nausea and vomiting after middle ear surgery in adults".

Study Centre: Institute of Anaesthesiology and Critical Care, Rajiv Gandhi Govt. General Hospital, Madras Medical College, Chennai 600003.

Participant Name: **Age:** **Sex:** **I.P. No:**

I confirm that I have understood the purpose of procedure for the above study. I have had the opportunity to ask questions and all my questions and doubts have been answered to my satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that the investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

Time:

Date:

Place:

Signature of the investigator: Signature/thumb impression of patient

Name of the investigator: Patient name

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு

செவியின் மத்திய பகுதி அறுவை சிகிச்சைக்கு பின் ஏற்படும் குமட்டல் மற்றும் வாந்தியினை தவிர்ப்பதற்காக வழங்கப்படும் காபாபென்டின் மற்றும் கிரானிசெட்ரான் மருந்துகளுக்கான ஒப்பீட்டு ஆய்வு.

ஆராய்ச்சியாளர் பெயர் : மரு.வெ.பாலகிருஷ்ணன்

பங்கேற்பாளர் பெயர் :

ஆராய்ச்சியின் நோக்கம் :

செவியின் மத்திய பகுதி அறுவை சிகிச்சைக்கு பின் ஏற்படும் குமட்டல் மற்றும் வாந்தியினை தவிர்ப்பதற்காக வழங்கப்படும் காபாபென்டின் மற்றும் கிரானிசெட்ரான் மருந்தின் திறனை விஷுவல் அனலாக் ஸ்கோரை பயன்படுத்தி அதன் தீவிரத்தை ஆய்வு செய்கிறேன்.

ஆய்வுமுறை

ஆய்வில் பங்குபெறும் நோயாளிகள் மூன்று குழுக்களாக பிரிக்கப்படுவர்.

குழு 1:அறுவை சிகிச்சைக்காக மயக்கம் கொடுக்கப்படுவதற்கு 3 நிமிடத்திற்கு முன்னால் கிரானிசெட்ரான் 3மி.கி சிரைநாளம் வழியாக பெறுபவர்கள்.

குழு2:அறுவை சிகிச்சைக்காக மயக்கம் கொடுப்பதற்கு 1 மணி நேரத்திற்கு முன்னதாக காபாபென்டின் 300மி.கி. வாய்வழியாக பெறுபவர்கள்.

ஆய்வின் நன்மைகள்

அறுவை சிகிச்சைக்கு பின் ஏற்படும் வாந்தி மற்றும் குமட்டலை தடுக்கிறது.

பக்கவிளைவுகள் :

தலைவலி, தலைச்சுற்றல் ஏற்படும் வாய்ப்பு உண்டு. அதனை சரி செய்வதற்கு தகுந்த சிகிச்சை அளிக்கப்படும்.

இந்த முறையான ஆய்வு ஏற்கனவே பல இடங்களில் நடத்தப்பட்டுள்ளது. மேலும் இதன் பாதுகாப்பு உறுதி செய்யப்பட்டுள்ளது. நீங்கள் இந்த ஆய்வில் பங்குகொள்ள் விரும்பவில்லை என்றால் எப்போதும் உபயோகப்படுத்தப்படும் மருந்தே கொடுக்கப்படும். உங்கள் பாதுகாப்பே எங்கள் முக்கிய நோக்கமாகும்.

இந்த ஆய்வு சம்பந்தமான எல்லா புள்ளி விவரங்கள் மற்றும் நோயாளிகளின் விவரங்கள் ரகசியமாக வைக்கப்படும. இந்த ஆய்வு சம்மந்தப்பட்ட எல்லா பரிசோதனைகள், மருந்துகள் மற்றும் மருத்துவ சேவைகள் அனைதும் நோயாளிகளுக்கு இலவசமாக வழங்கப்படும்.

ஆய்வாளரின் கையொப்பம் **பங்கேற்பாளர் கையொப்பம்**

நாள் :

இடம் :

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சி தலைப்பு

செவியின் மத்திய பகுதி அறுவை சிகிச்சைக்கு பின் ஏற்படும் குமட்டல் மற்றும் வாந்தியினை தவிர்ப்பதற்காக வழங்கப்படும் காபாபென்டின் மற்றும் கிரானிசெட்ரான் மருந்துகளுக்கான ஒப்பீட்டு ஆய்வு.

ஆய்வு நிலையம் : மயக்கவியல் துறை, சென்னை மருத்துவக் கல்லூரி சென்னை - 3.

பங்கு பெறுவரின் பெயர் :

பங்குபெறுபவரின் எண் :

பங்குபெறுபவர் இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது. ☐

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன். ☐

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். ☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கின்றேன். ☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன் 'இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிகிறேன். ☐

பங்கேற்பவரின் கையொப்பம் ..... இடம்..... தேதி.....

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் ..... இடம்..... தேதி.....

ஆய்வாளரின் பெயர் .....

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr.V.Balakrishnan
Postgraduate M.D.(Anaesthesiology)
Madras Medical College
Chennai 600 003

Dear Dr.V.Balakrishnan,

The Institutional Ethics Committee has considered your request and approved your study titled **"Compare the effects of Intravenous Granisetron and oral gabapentin in preventing post operative nausea and vomiting after middle ear surgery in adults" No.02082015.**

The following members of Ethics Committee were present in the meeting held on 04.08.2015 conducted at Madras Medical College, Chennai-3.

1. Prof.C.Rajendran, M.D.,	: Chairperson
2. Prof.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3. Prof.Sudha Seshayyan, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4. Prof.B.Vasanthi, M.D., Professor Pharmacology, MMC	: Member
5. Prof.A.Rajendran, M.S., Professor, Inst.of Surgery, MMC	: Member
6. Prof.Saraswathy, M.D., Director, Inst. Of Pathology, MMC	: Member
7. Prof.Srinivasagalu, Director, Inst.of Inter Med. MMC	: Member
8. Tmt. J.Rajalakshmi, J.A.O. MMC, Ch-3	: Lay Person
9. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
10. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

POST OPERATIVE VAS SCORE - GRANISETRON

S. NO	NAME	AGE	SEX	BMI	DIAGNOSIS	ASA	0 HR	1 HR	1.5 HR	2 HR	2.5 HR	3 HR	3.5 HR	4 HR	4.5 HR	5 HR	5.5 HR	6 HR	8 HR	10 HR	12 HR	14 HR	16 HR	20 HR	24 HR
1	Siva	23	F	25	Chronic Otitis Media	1	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	2	2	2	2
2	Balakumar	24	F	24	Cholesteatoma	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	2	2
3	Ponnummal	25	M	24	Otosclerosis	2	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	2	2	2	2
4	Nirmala	32	F	23	Cholesteatoma	2	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	2	2
5	Dhanam	42	M	26	Otosclerosis	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1
6	Rose	21	F	21	Otosclerosis	2	0	0	0	0	0	0	0	1	1	1	1	1	2	2	2	2	2	2	3
7	Sangeetha	39	M	23	Chronic Otitis Media	2	0	0	0	0	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3
8	Selvi	44	M	22	Cholesteatoma	1	0	0	0	0	0	1	1	1	2	2	3	3	4	5	0	0	0	0	0
9	Natarajan	25	F	26	Otosclerosis	2	0	0	0	0	0	0	0	0	0	0	1	1	1	1	2	2	2	3	3
10	Sekar	45	F	26	Chronic Otitis Media	1	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	2
11	Kanimozhi	27	F	26	Chronic Otitis Media	2	0	0	0	0	0	0	0	0	0	0	1	1	1	1	2	2	2	2	2
12	Sudha	28	F	22	Chronic Otitis Media	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	2
13	Ravi	32	M	27	Chronic Otitis Media	2	0	0	0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	3
14	Thilagam	43	M	24	Chronic Otitis Media	1	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	2	2	2
15	Asaithambi	38	F	27	Otosclerosis	2	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	2	2	2	2
16	Vijayakumari	24	M	24	Otosclerosis	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1
17	Nagarathinam	46	F	24	Chronic Otitis Media	2	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	2	2
18	Girija	37	M	22	Glomous tympanicum	2	0	0	0	1	1	1	1	2	2	2	2	3	4	5	0	0	0	0	0
19	Manikavel	29	M	26	Cholesteatoma	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1
20	Rajagopal	32	F	25	Chronic Otitis Media	2	0	0	0	0	0	1	1	1	1	1	1	1	2	2	2	2	2	3	3
21	Munusamy	26	M	25	Chronic Otitis Media	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1
22	Sumathy	49	F	21	Chronic Otitis Media	2	0	0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	3	3
23	Parvathy	35	M	23	Chronic Otitis Media	2	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	2	2
24	Kalyani	41	F	23	Chronic Otitis Media	1	0	0	0	0	0	1	1	1	1	1	1	1	2	2	2	2	2	3	3
25	Devandran	47	M	25	Chronic Otitis Media	2	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	2
26	Thirumaran	33	M	26	Chronic Otitis Media	1	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	2	2
27	Kalaiyanaga	42	F	26	Chronic Otitis Media	2	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1
28	Malarvizhi	49	M	21	Chronic Otitis Media	1	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	2	2	2	2
29	Kavitha	36	F	24	Chronic Otitis Media	1	0	0	0	0	0	0	0	0	0	1	1	1	1	1	2	2	2	2	3
30	Sundari	31	M	22	Cholesteatoma	1	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	2

					POST OP HEMODYNAMICS HEART RATE - GRANISETRON																			
S. NO	NAME	AGE	SEX	BMI	DIAGNOSIS	ASA	0 HR	1 HR	1.5 HR	2 HR	2.5 HR	3 HR	3.5 HR	4 HR	4.5 HR	5 HR	5.5 HR	6 HR	8 HR	10 HR	12 HR	14 HR	16 HR	20 HR	24 HR
1	Siva	23	F	25	Chronic Otitis Media	1	69	72	71	70	74	75	72	70	71	71	69	64	65	63	67	67	68	64	68
2	Balakumar	24	F	24	Cholesteatoma	1	78	75	75	74	75	74	78	76	72	73	72	73	70	71	74	74	72	74	71
3	Ponnummal	25	M	24	Otosclerosis	2	66	65	66	65	66	66	64	68	65	60	62	62	62	63	62	63	62	63	62
4	Nirmala	32	F	23	Cholesteatoma	2	68	63	63	63	62	60	60	61	64	65	62	63	64	65	67	65	62	64	62
5	Dhanam	42	M	26	Otosclerosis	1	64	60	62	65	62	62	63	62	63	62	62	60	62	62	65	64	64	64	62
6	Rose	21	F	21	Otosclerosis	2	76	72	70	71	71	70	73	73	72	73	72	75	76	75	78	75	78	72	73
7	Sangeetha	39	M	23	Chronic Otitis Media	2	78	74	72	72	72	70	71	71	71	74	72	75	75	76	72	70	74	75	70
8	Selvi	44	M	22	Cholesteatoma	1	64	60	62	62	62	64	63	68	61	60	62	64	75	78	69	68	66	62	63
9	Natarajan	25	F	26	Otosclerosis	2	85	80	86	86	86	85	87	82	80	80	81	82	80	84	85	79	79	78	79
10	Sekar	45	F	26	Chronic Otitis Media	1	86	82	82	80	82	81	80	82	73	79	75	75	72	78	80	81	82	84	80
11	Kanimozhi	27	F	26	Chronic Otitis Media	2	64	66	64	64	65	64	66	63	62	61	67	66	66	64	65	68	62	66	67
12	Sudha	28	F	22	Chronic Otitis Media	1	80	75	77	78	75	75	72	74	75	75	76	72	74	75	78	72	75	75	74
13	Ravi	32	M	27	Chronic Otitis Media	2	82	77	77	75	74	75	76	74	74	75	74	78	79	74	74	75	74	72	70
14	Thilagam	43	M	24	Chronic Otitis Media	1	76	76	74	72	70	70	70	72	72	72	72	71	74	74	75	75	75	74	74
15	Asaithambi	38	F	27	Otosclerosis	2	60	64	60	63	62	63	62	63	62	64	63	64	66	67	68	68	62	62	64
16	Vijayakumari	24	M	24	Otosclerosis	1	72	67	68	68	65	68	66	62	62	62	63	64	65	65	66	61	62	60	62
17	Nagarathinam	46	F	24	Chronic Otitis Media	2	64	66	66	67	62	60	63	60	60	60	62	61	64	65	66	66	62	64	62
18	Girija	37	M	22	Glomous tympanicum	2	85	81	80	79	77	77	78	75	76	73	72	72	88	99	89	83	83	82	80
19	Manikavel	29	M	26	Cholesteatoma	1	63	60	60	61	62	65	62	61	62	63	64	62	63	62	62	61	60	58	59
20	Rajagopal	32	F	25	Chronic Otitis Media	2	65	62	61	60	62	61	60	65	64	65	62	60	61	63	62	61	60	64	67
21	Munusamy	26	M	25	Chronic Otitis Media	1	83	80	82	84	80	80	79	78	78	78	72	74	75	74	74	72	70	71	72
22	Sumathy	49	F	21	Chronic Otitis Media	2	60	58	55	56	56	54	52	56	56	56	56	58	58	56	57	57	58	58	57
23	Parvathy	35	M	23	Chronic Otitis Media	2	82	78	78	78	76	75	75	72	72	74	75	75	75	76	76	72	77	74	74
24	Kalyani	41	F	23	Chronic Otitis Media	1	72	74	74	74	75	74	68	69	62	68	68	64	65	61	66	66	65	65	62
25	Devandran	47	M	25	Chronic Otitis Media	2	54	58	54	58	59	59	49	57	51	55	53	59	59	57	60	61	59	59	58
26	Thirumaran	33	M	26	Chronic Otitis Media	1	75	74	74	74	75	74	75	76	78	79	72	72	73	74	75	76	75	74	72
27	Kalaiyanaga	42	F	26	Chronic Otitis Media	2	75	72	72	72	70	71	74	74	75	76	75	75	75	74	72	72	70	71	70
28	Malarvizhi	49	M	21	Chronic Otitis Media	1	76	70	72	72	72	74	72	74	70	71	72	73	73	73	75	75	74	74	72
29	Kavitha	36	F	24	Chronic Otitis Media	1	78	72	72	72	74	74	74	70	78	78	75	75	75	78	78	75	74	74	73
30	Sundari	31	M	22	Cholesteatoma	1	72	68	68	69	66	66	64	64	64	62	62	63	63	65	65	65	66	62	64

	postoperative systolic bp GRANISETRON																							
							POSTOPERATIVE MEAN ARTERIAL PRESSURE GRANISETRON																	
S. NO	NAME	AGE	SEX	BMI	DIAGNOSIS	ASA	0 HR	1 HR	1.5 HR	2 HR	2.5 HR	3 HR	3.5 HR	4 HR	4.5 HR	5 HR	5.5 HR	6 HR	8 HR	10 HR	12 HR	14 HR	16 HR	20 HR	24 HR
1	sundhari	23	F	25	Chronic Otitis Media	1	99	95	91	92	91	91	91	92	91	92	92	91	90	91	93	90	91	91	90
2	balasundhari	24	F	24	Cholesteatoma	1	94	90	89	89	87	85	83	85	85	85	85	86	85	84	87	87	87	86	90
3	bala	25	M	24	Otosclerosis	2	84	83	80	82	81	85	86	86	86	85	88	88	89	87	86	84	81	80	79
4	Nirmala	32	F	23	Cholesteatoma	2	89	86	87	85	87	84	85	85	85	83	84	86	88	86	86	85	85	88	85
5	thiyagu	42	M	26	Otosclerosis	1	98	96	95	95	95	95	95	92	93	96	96	97	94	93	95	97	94	95	94
6	Rose	21	F	21	Otosclerosis	2	98	92	91	91	91	90	90	90	92	91	91	91	92	89	88	88	93	94	96
7	selvam	39	M	23	Chronic Otitis Media	2	97	91	92	92	92	92	95	95	95	97	97	94	95	91	92	90	91	93	91
8	hari	44	M	22	Cholesteatoma	1	99	93	95	96	93	92	92	92	91	92	93	92	113	101	95	94	96	95	93
9	shanthi	25	F	26	Otosclerosis	2	89	86	86	87	85	85	87	89	87	88	86	84	85	83	85	88	85	85	86
10	selvi	45	F	26	Chronic Otitis Media	1	81	79	79	79	76	80	82	83	84	79	81	80	82	84	80	82	76	77	78
11	Kanimozhi	27	F	26	Chronic Otitis Media	2	84	85	86	86	87	84	83	85	85	85	85	85	84	87	87	89	84	86	85
12	Sudha	28	F	22	Chronic Otitis Media	1	90	89	87	87	88	87	88	85	86	84	86	85	83	83	83	84	83	84	85
13	Ravi	32	M	27	Chronic Otitis Media	2	86	88	89	87	88	87	86	37	87	85	86	86	89	88	90	88	88	88	86
14	thirumurugan	43	M	24	Chronic Otitis Media	1	91	86	86	86	86	87	87	88	88	88	88	89	89	91	88	88	89	86	86
15	subha	38	F	27	Otosclerosis	2	104	100	100	98	97	98	98	99	99	97	99	99	100	100	103	100	101	100	99
16	Vijayakumar	24	M	24	Otosclerosis	1	94	91	90	93	89	90	92	90	93	92	93	90	91	91	89	90	87	93	92
17	Nagarathinam	46	F	24	Chronic Otitis Media	2	96	91	91	90	89	88	89	93	94	92	92	92	92	89	89	89	88	89	88
18	Giri	37	M	22	Glomous tympanicum	2	87	85	88	86	86	85	85	83	84	87	87	85	105	94	85	85	85	84	85
19	Manikavel	29	M	26	Cholesteatoma	1	102	96	95	94	93	97	95	96	91	94	96	93	98	94	101	95	98	93	94
20	Roja	32	F	25	Chronic Otitis Media	2	101	94	95	96	93	91	95	93	92	93	93	93	92	91	91	92	89	90	91
21	Munusamy	26	M	25	Chronic Otitis Media	1	105	99	97	98	98	98	97	93	93	92	96	93	95	92	93	95	96	98	97
22	Sumathy	49	F	21	Chronic Otitis Media	2	94	94	90	89	93	92	93	94	93	94	92	93	95	97	93	96	95	96	96
23	Parthiban	35	M	23	Chronic Otitis Media	2	82	83	84	84	82	85	84	84	83	82	82	81	86	84	87	89	87	88	87
24	Kalyani	41	F	23	Chronic Otitis Media	1	75	77	77	76	76	77	75	77	75	76	74	75	78	79	81	79	79	78	78
25	Devandran	47	M	25	Chronic Otitis Media	2	80	79	75	74	75	76	74	73	75	77	75	70	72	74	75	77	73	74	75
26	Thirumaran	33	M	26	Chronic Otitis Media	1	92	87	88	88	88	91	88	92	90	89	89	84	83	84	87	88	89	87	88
27	kanaga	42	F	26	Chronic Otitis Media	2	93	89	88	88	87	87	86	87	92	91	92	92	93	92	89	89	93	91	91
28	mahesh	49	M	21	Chronic Otitis Media	1	85	88	88	88	89	91	92	90	90	90	91	90	88	89	85	87	86	86	85
29	Kavitha	36	F	24	Chronic Otitis Media	1	88	86	82	87	87	87	83	84	84	84	85	86	87	89	86	87	86	86	85
30	sundharan	31	M	22	Cholesteatoma	1	98	96	97	95	96	95	95	97	93	96	93	93	94	94	93	93	93	93	94

					POST OPERATIVE VAS SCORE - GABAPENTIN																				
S. NO	NAME	AGE	SEX	BMI	DIAGNOSIS	ASA	0 HR	1 HR	1.5 HR	2 HR	2.5 HR	3 HR	3.5 HR	4 HR	4.5 HR	5 HR	5.5 HR	6 HR	8 HR	10 HR	12 HR	14 HR	16 HR	20 HR	24 HR
1	balaji	24	M	25	CSOM	1	0	0	0	1	1	2	2	3	3	4	4	5	0	0	0	0	0	1	1
2	karthick	42	M	24	Chronic Otitis Media	2	0	0	0	0	0	1	1	1	2	2	3	3	3	3	4	4	4	4	4
3	arun	25	M	25	Otosclerosis	1	0	0	0	0	0	0	1	1	1	1	1	2	2	2	2	2	3	3	3
4	Anbalagan	43	M	24	Facial Nerve palsy	2	0	0	1	1	1	1	2	2	2	2	3	3	3	4	4	4	4	4	4
5	chitra	22	F	25	Glo	1	0	0	0	0	0	1	1	1	1	1	2	2	2	2	2	3	3	4	4
6	Nirmala	38	F	24	CSOM	2	0	1	1	1	1	1	2	2	2	3	3	3	4	4	5	0	0	0	0
7	Rajakumari	41	F	26	Facial Nerve palsy	1	0	0	0	0	1	1	1	2	2	2	3	3	3	3	3	4	4	4	4
8	vijay	26	M	20	CSOM	2	0	0	0	1	1	2	2	2	2	2	2	3	3	3	3	3	4	4	4
9	Nithya	45	F	22	Glomous tympanicum	2	0	0	0	0	0	0	0	1	1	1	1	1	2	2	2	2	2	3	3
10	devan	25	M	21	Chronic Otitis Media	2	0	0	0	0	0	1	1	1	2	2	2	2	3	3	3	4	4	4	4
11	Remesh	27	M	24	CSOM	1	0	0	0	0	1	1	1	1	2	2	2	2	3	3	4	4	4	4	4
12	srinivasan	32	M	23	Otosclerosis	1	0	0	0	1	1	1	2	2	2	3	3	4	4	4	4	4	4	4	4
13	Gopalan	28	M	25	Glomous tympanicum	1	0	0	0	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	4
14	Sujatha	44	F	22	CSOM	2	0	0	0	0	0	0	1	1	1	1	2	2	2	3	3	3	3	4	4
15	Latha	33	F	25	Chronic Otitis Media	2	0	0	0	0	0	0	1	1	1	2	2	2	3	3	3	3	3	3	3
16	metha	21	M	24	Otosclerosis	1	0	0	0	0	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2
17	Kumarevel	38	M	25	Chronic Otitis Media	2	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2	3	3	4
18	krishnaveni	29	F	26	Otosclerosis	2	0	0	0	0	1	1	1	1	2	2	2	2	3	3	4	4	4	4	4
19	Rani	46	F	25	CSOM	1	0	1	1	1	2	2	2	3	4	4	4	4	4	4	4	4	4	4	4
20	mari	38	M	25	Chronic Otitis Media	2	0	0	0	0	1	1	1	1	2	2	2	2	2	2	3	3	3	3	3
21	muthu	26	M	26	Chronic Otitis Media	1	1	1	1	1	2	2	3	3	4	4	5	0	0	0	0	0	0	1	1
22	Saroja	36	F	26	CSOM	2	0	0	0	0	0	0	1	1	1	2	2	3	3	4	4	4	4	4	4
23	Kalaivani	48	F	25	Chronic Otitis Media	1	0	0	0	1	1	1	1	2	2	2	3	3	3	3	4	4	4	4	4
24	arul	32	M	22	Chronic Otitis Media	2	0	0	0	0	1	1	1	1	1	1	2	2	2	2	3	3	3	3	3
25	mahendran	43	M	24	Chronic Otitis Media	1	0	0	1	1	1	1	2	2	3	4	4	5	0	0	0	0	0	0	1
26	neelaveni	33	F	24	CSOM	2	0	0	0	1	1	2	2	3	3	4	5	0	0	0	0	0	1	1	2
27	gayathri	46	F	25	Chronic Otitis Media	1	0	0	0	0	0	0	1	1	1	2	2	2	3	3	4	4	4	4	4
28	shanthi	35	F	24	Chronic Otitis Media	1	0	0	0	0	1	1	1	1	2	2	2	3	3	3	4	4	4	4	4
29	Andal	49	F	25	CSOM	1	0	0	0	1	1	1	2	2	2	3	4	5	0	0	0	0	0	0	0
30	anbarasi	31	F	24	Chronic Otitis Media	2	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	4	4	4	4

					POST OPERATIVE HEMODYNAMICS HEART RATE - GABAPENTIN																			
S. NO	NAME	AGE	SEX	BMI	DIAGNOSIS	ASA	0 HR	1 HR	1.5 HR	2 HR	2.5 HR	3 HR	3.5 HR	4 HR	4.5 HR	5 HR	5.5 HR	6 HR	8 HR	10 HR	12 HR	14 HR	16 HR	20 HR	24 HR
1	balaji	24	M	25	CSOM	1	110	106	98	98	99	100	95	91	92	99	104	101	94	92	93	96	92	97	96
2	karthick	42	M	24	Chronic Otitis Media	2	95	92	90	88	87	88	85	83	81	84	87	88	88	86	89	82	79	84	85
3	arun	25	M	25	Otosclerosis	1	86	82	83	80	84	88	82	82	84	85	85	80	81	82	79	77	78	81	84
4	Anbalagan	43	M	24	Facial Nerve palsy	2	77	79	74	75	78	73	73	72	75	75	74	76	78	78	77	79	81	78	78
5	chitra	22	F	25	Glo	1	80	80	77	73	74	74	75	74	76	73	72	74	75	73	72	74	77	79	76
6	Nirmala	38	F	24	CSOM	2	74	70	71	68	68	70	71	77	82	85	80	77	75	73	74	72	72	72	74
7	Rajakumari	41	F	26	Facial Nerve palsy	1	80	78	75	75	75	76	74	72	74	76	78	75	75	77	76	73	78	75	77
8	vijay	26	M	20	CSOM	2	90	88	86	85	83	89	84	84	85	87	85	88	85	86	86	82	82	84	84
9	Nithya	45	F	22	Glomous tympanicum	2	77	75	75	74	74	70	71	76	72	69	68	71	72	70	70	72	72	72	74
10	devan	25	M	21	Chronic Otitis Media	2	85	85	83	80	81	82	75	77	78	78	77	79	80	82	80	81	84	85	85
11	Remesh	27	M	24	CSOM	1	76	74	75	75	72	71	70	78	78	79	83	82	85	85	82	88	86	87	84
12	srinivasan	32	M	23	Otosclerosis	1	90	82	81	84	80	76	79	77	81	84	84	83	86	87	88	84	80	79	74
13	Gopalan	28	M	25	Glomous tympanicum	1	72	70	64	66	68	64	65	66	68	64	66	65	64	64	66	62	68	67	66
14	Sujatha	44	F	22	CSOM	2	78	76	74	74	76	75	73	72	72	74	76	78	75	74	78	72	70	74	72
15	Latha	33	F	25	Chronic Otitis Media	2	85	80	82	78	76	74	74	75	75	74	73	71	75	75	76	74	74	75	76
16	metha	21	M	24	Otosclerosis	1	83	77	75	75	76	72	74	75	76	72	74	75	73	77	76	78	74	71	72
17	Kumarevel	38	M	25	Chronic Otitis Media	2	82	82	84	80	76	77	78	74	75	74	74	71	72	73	75	70	71	72	74
18	krishnaveni	29	F	26	Otosclerosis	2	88	84	85	84	86	87	82	82	81	84	83	82	86	84	85	80	79	88	84
19	Rani	46	F	25	CSOM	1	102	96	93	91	90	94	95	99	99	98	100	102	96	94	92	90	92	92	90
20	mari	38	M	25	Chronic Otitis Media	2	87	85	85	84	82	80	78	76	80	78	79	80	82	84	81	79	76	80	79
21	muthu	26	M	26	Chronic Otitis Media	1	88	82	80	82	84	84	83	82	84	88	89	86	85	85	84	84	82	81	80
22	Saroja	36	F	26	CSOM	2	70	68	68	66	70	71	72	74	70	69	68	66	67	69	70	72	71	70	67
23	Kalaivani	48	F	25	Chronic Otitis Media	1	78	73	71	70	72	70	70	72	73	74	70	70	72	72	73	74	74	74	76
24	arul	32	M	22	Chronic Otitis Media	2	69	65	66	64	63	64	64	66	62	63	64	65	66	67	66	64	68	68	62
25	mahendran	43	M	24	Chronic Otitis Media	1	79	76	75	75	73	72	76	76	78	79	82	82	80	82	81	84	84	80	82
26	neelaveni	33	F	24	CSOM	2	74	76	76	77	78	72	71	70	75	76	80	79	77	76	78	77	76	74	75
27	gayathri	46	F	25	Chronic Otitis Media	1	74	71	70	67	69	70	72	74	75	70	72	71	71	68	69	68	70	72	72
28	shanthi	35	F	24	Chronic Otitis Media	1	77	70	75	74	75	74	76	73	72	70	72	78	75	74	72	69	72	74	78
29	Andal	49	F	25	CSOM	1	85	80	81	80	82	80	81	79	86	84	85	82	83	84	80	78	81	79	80
30	anbarasi	31	F	24	Chronic Otitis Media	2	80	73	75	74	74	74	76	77	73	72	74	74	76	75	73	74	74	72	70

				Postoperative Mean Arterial Pressure Gabapentin																				
S. NO	NAME	AGE	SEX	BMI	DIAGNOSIS	ASA	24 HR	0 HR	1 HR	1.5 HR	2 HR	2.5 HR	3 HR	3.5 HR	4 HR	4.5 HR	5 HR	5.5 HR	6 HR	8 HR	10 HR	12 HR	14 HR	16 HR	20 HR	24 HR
1	balaji	24	M	25	CSOM	1	83	97	93	91	92	95	92	93	92	94	96	107	105	101	97	97	94	95	95	96
2	karthick	42	M	24	Chronic Otitis Media	2	80	104	97	94	98	94	95	91	90	91	90	91	93	88	87	89	91	93	92	93
3	arun	25	M	25	Otosclerosis	1	74	97	90	87	87	87	83	85	84	83	82	83	85	82	83	85	87	88	85	87
4	Anbalagan	43	M	24	Facial Nerve palsy	2	62	89	85	82	83	84	82	81	81	81	85	83	81	82	82	78	79	77	76	76
5	chitra	22	F	25	Glo	1	81	104	99	97	98	99	95	94	93	93	95	95	98	95	99	94	94	92	93	92
6	Nirmala	38	F	24	CSOM	2	71	90	89	85	85	85	86	84	84	81	82	82	87	101	99	93	90	90	90	91
7	Rajakumari	41	F	26	Facial Nerve palsy	1	71	91	85	85	86	86	87	87	84	86	87	85	85	85	87	85	85	86	84	83
8	vijay	26	M	20	CSOM	2	70	94	90	91	91	90	87	85	87	85	84	83	85	84	84	84	86	85	83	84
9	Nithya	45	F	22	Glomous tympanicum	2	78	104	97	95	93	94	94	93	93	89	89	89	86	91	92	94	92	91	92	90
10	devan	25	M	21	Chronic Otitis Media	2	74	92	90	88	88	88	87	88	88	90	93	88	88	90	86	87	87	87	86	86
11	Remesh	27	M	24	CSOM	1	88	100	92	91	90	91	88	93	94	95	94	93	93	93	95	95	102	108	100	97
12	srinivasan	32	M	23	Otosclerosis	1	83	99	91	92	90	92	91	90	90	92	94	90	91	89	91	92	106	101	98	92
13	Gopalan	28	M	25	Glomous tympanicum	1	72	97	91	88	88	87	85	84	87	88	85	84	83	83	84	84	83	81	82	84
14	Sujatha	44	F	22	CSOM	2	71	93	87	86	85	85	90	85	85	85	86	86	82	86	85	85	87	86	86	86
15	Latha	33	F	25	Chronic Otitis Media	2	82	107	101	99	97	98	98	96	95	94	96	93	94	92	91	94	93	95	94	94
16	metha	21	M	24	Otosclerosis	1	81	103	94	92	92	92	91	89	89	89	89	87	87	88	87	90	90	89	88	89
17	Kumarevel	38	M	25	Chronic Otitis Media	2	74	97	90	89	87	88	90	87	89	87	86	91	85	91	89	87	85	87	87	87
18	krishnaveni	29	F	26	Otosclerosis	2	70	98	91	90	91	91	91	89	89	87	86	85	87	84	85	86	85	83	84	80
19	Rani	46	F	25	CSOM	1	73	97	89	85	86	86	86	88	87	89	90	104	107	95	89	88	91	89	89	87
20	mari	38	M	25	Chronic Otitis Media	2	73	96	89	88	88	87	84	86	86	89	86	88	88	89	89	87	89	88	88	89
21	muthu	26	M	26	Chronic Otitis Media	1	80	98	92	91	92	94	96	95	92	87	91	99	105	95	93	92	92	89	90	89
22	Saroja	36	F	26	CSOM	2	74	95	90	91	91	91	90	89	87	87	88	87	86	87	83	83	83	84	84	88
23	Kalaivani	48	F	25	Chronic Otitis Media	1	71	94	88	89	88	89	88	86	87	86	86	90	87	87	88	90	87	89	85	85
24	arul	32	M	22	Chronic Otitis Media	2	70	87	81	83	81	81	82	80	81	81	83	85	83	87	82	82	81	81	83	80
25	mahendran	43	M	24	Chronic Otitis Media	1	69	97	87	84	84	85	86	87	88	91	105	101	95	89	89	89	85	85	86	84
26	neelaveni	33	F	24	CSOM	2	71	93	86	84	85	82	83	85	83	86	84	97	94	90	87	86	85	83	84	84
27	gayathri	46	F	25	Chronic Otitis Media	1	70	87	87	87	85	84	84	85	87	86	89	88	85	84	83	82	82	85	84	83
28	shanthi	35	F	24	Chronic Otitis Media	1	72	90	85	84	86	85	85	87	86	84	82	80	85	87	86	88	85	87	85	85
29	Andal	49	F	25	CSOM	1	70	81	77	77	79	80	79	78	81	80	80	83	91	92	86	85	83	82	81	81
30	anbarasi	31	F	24	Chronic Otitis Media	2	69	84	83	83	81	83	83	83	85	80	82	81	82	77	79	78	77	77	81	82